ATTACHMENT 34

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., *Plaintiff/Counter-Defendant,* v. INTUITIVE SURGICAL, INC., *Defendant/Counter-Claimant.*	Case No. 3:21-cv-03496-VC Honorable Vince Chhabria Complaint filed: May 10, 2021

OPENING EXPERT REPORT OF PHILIP J. PHILLIPS

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY

DECEMBER 2, 2022

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I. Scope of Engagement and Summary of Opinions

1. I understand that this is an antitrust case pending before U.S. District Court in the Northern District of California in which Plaintiff Surgical Instrument Service Company, Inc, ("SIS") alleges causes of action against Defendant Intuitive Surgical, Inc. ("Intuitive Surgical" or "ISI") for engaging in alleged anti-competitive practices that caused financial harm to SIS.

2. I have been retained by Haley Guiliano L.L.P. ("HG") to assist HG on behalf of SIS and provide expert consulting service with respect to the case. My Report and the opinions expressed herein are based on my experience with and knowledge of the Food, Drug and Cosmetic Act ("FDCA"), Food and Drug Administration ("FDA") regulation and practice, and my assessment of the evidence in this matter. I am not an attorney. Throughout this Report, I refer to and provide my opinions on the reasonableness of SIS's efforts to conform with all applicable FDA regulatory requirements in regard to servicing Intuitive Surgical's EndoWrists. I also provide context for understanding and evaluating SIS's efforts to conform to applicable regulatory requirements. Finally, I refer to and provide my opinions on whether certain communications Intuitive is alleged to have made to customers suggesting SIS's servicing of Intuitive Surgical's EndoWrist instruments is contrary to FDA regulations and/or possibly illegal are false and misleading.

3. A list of materials that I was given access to and from which I sourced the materials I considered is attached to this report as **EXHIBIT 1**.

4. Based on my experience and the evidence in this case, and for the reasons explained below, in my opinion, SIS acted reasonably in its effort to conform with FDA medical device requirements. In particular:

   i. It was reasonable for SIS to conclude that its commercial activities did not constitute "remanufacturing" as defined by the Quality System Regulation;

   ii. SIS's decision to engage in its commercial activities without FDA authorization was reasonable;

iii. the submission of a 510(k) and an FDA clearance by others does not establish that either is in fact, necessary or required for SIS's repair services; and

iv. Intuitive Surgical's customer communications alleged in SIS's Complaint and court filings are simply false and misleading.

5. I am being compensated for my work at a rate of $500 per hour. My compensation is not dependent on the outcome of this case or the opinions I render in this or any other report or declaration I submit in this matter.

6. I reserve the right to respond to any arguments or evidence offered in response to the opinions and topics discussed in this Report as well as to the opening reports served by Intuitive Surgical's expert witnesses.

II. Qualifications

7. I am currently the President of Phillips Consulting Group, LLC, located in Silver Spring, Maryland, where I provide strategic and regulatory consulting services to clients and their counsel on public health related issues, with a focus on managing issues related to FDA regulation of medical devices and combination products. I have over 40 years of experience in FDA regulation of medical devices, with a focus on the development and implementation of regulatory strategies to achieve compliance with FDA requirements regarding the design, manufacture, and distribution of medical devices and combination products containing medical devices.

8. I earned a Bachelor of Science degree from the University of Maryland in 1976, and a Master of Business Administration from the George Washington University School of Government and Business Administration in 1982.

9. I was employed by FDA in various capacities from 1981 through 2005. From 1981 through 1984, I served as an Interdisciplinary Scientist in the Division of Ophthalmic Devices ("DOD") in the Office of Device Evaluation ("ODE").[1] From 1984 through 1987, I served as the

[1] There was a reorganization within FDA's Center for Devices and Radiological Heath ("CDRH") in 2019 that resulted in a change in the name of many organizational units and some delegations of authority. DOD is now part of the Office of Health Technology 1 ("OHT 1"): Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices) and ODE is referred to as the Office of Product Evaluation and Quality ("OPEQ").

Branch Chief of the Surgical and Diagnostic Devices Branch in DOD and as the Deputy Director of DOD from 1986 through 1987.

10. From 1987 through 1994, I served as the Director of Program Operations[2] in ODE where I had responsibility for directing the Premarket Notification ("510(k)") program and Premarket Approval ("PMA") program, among other premarket regulatory programs. I also served as the Interim Director of ODE's Division of General and Restorative Devices[3] in 1993.

11. From 1994 through 2005, I served as the Deputy Director of Science and Regulatory Policy in ODE. As Deputy Director of Science and Regulatory Policy, I played a leadership role in the organizational unit in FDA that is responsible for the premarket evaluation and market authorization of all medical devices intended for commercial distribution in the United States. As ODE's chief scientific and regulatory policy-maker, I planned, managed, and directed all premarket review programs that ensure the safety and effectiveness of medical devices marketed and used in the U.S. My role as a Deputy Director in ODE required me to manage and direct six review divisions that encompassed all medical specialties, three support staffs, and a total work force of over 300 scientists, engineers, and clinicians.

12. In 2005, I left FDA to become a private consultant, joining Becker & Associates Consulting, Inc., a Washington, D.C.-based regulatory consulting firm, as the Executive Vice President and Director of the Medical Device Practice. In that capacity, I provided consulting services to industry and legal counsel on complex FDA-related matters until I formed the Phillips Consulting Group in 2009, through which I continued to provide consulting services to industry and legal counsel on complex FDA-related matters.

13. Although the focus of my business is on assisting companies in achieving FDA authorization to market innovative medical devices and combination products containing medical devices in the United States, and ensuring compliance with FDA requirements, I occasionally serve as an expert witness in legal proceedings that involve medical devices and combination products.

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[2] Currently part of the Division of Regulatory Programs 1.

[3] Currently part of the Office of Health Technology 4 (OHT 4): Surgical and Infection Control Devices.

A list of the cases in which I have been deposed or provided testimony as an expert over the last five (5) years is attached to this Report as **EXHIBIT 2**.

14. I am a registered clinical microbiologist with the American Society for Clinical Pathology ("ASCP") Board of Registry. I am also an active member of the Food and Drug Law Institute ("FDLI") and former Chairman of FDLI's Medical Device Committee, as well as a member of the Regulatory Affairs Professional Society ("RAPS"). A complete list of my memberships in professional organizations, selected presentations, and other experience in the medical device and regulatory fields is set forth in my resume.

15. My current resume, which provides additional detail on my qualifications and background, is attached to this Report as **EXHIBIT 3**.

III. Background on Regulation of Devices

16. FDA is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, biological products, medical devices, foods, cosmetics, and products that emit radiation.[4] FDA is also responsible for promoting the public health by helping to speed innovations that make medicines, medical devices, foods, and radiation-emitting products safer, more effective, and more affordable, and helping the public to obtain accurate, science-based information necessary to use medicines, medical devices, foods, and radiation-emitting products to safeguard their health.

17. The word "device" is defined by law,[5] as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within

[4] 21 U.S.C. § 393(b).
[5] 21 U.S.C. § 321(h).

or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o). A device, as that term is defined, is basically a healthcare product that fulfills its medical purpose by physical and/or mechanical means, rather than through chemical and/or metabolic activity.

18. Although the definition of the term "device" includes "any component, part, or accessory," in reality FDA does not actively regulate all device components, parts, and accessories but rather focuses its attention on those that are "ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose …" [21 CFR § 820.20(a)(6)]. Illustrations of components regulated by FDA that are cited include blood filters and dialysis tubing that are required for device functionality and are packaged, labeled and are commercially distributed directly to users. From a quality systems standpoint, the term "component" is defined more broadly to include the term "part" [21 CFR § 820.3(c)], however the relevance of the definition pertains to device manufacturers' responsibilities to ensure that any components and parts incorporated into a finished device are suitable for their intended purpose and fulfill relevant requirements. Very few device components and parts are subject to registration and listing requirements and premarket notification.

19. Medical devices are regulated by FDA through a classification system based on the risk(s) posed by the product, the existing knowledge related to the product's intended use and technology, and the level of regulatory control needed to adequately assure safety and effectiveness.[6]

20. The objective of FDA device regulation is to provide the American public with reasonable assurance of the safety and effectiveness for all medical devices introduced into interstate commerce.[7] The basic framework for achieving this objective rests on a classification system in which a particular device's class designation dictates the applicable regulatory

[6] 21 U.S.C. § 360c.
[7] 21 U.S.C. § 393(b).

requirements. FDA's approach to assuring safety and effectiveness depends upon the class of the device, and varies with the level of concern that FDA has regarding the adequacy of the available regulatory controls to provide this assurance.

21. The Federal Food, Drug, and Cosmetics Act ("FDCA" or "the Act")[8] defines three classes of medical devices: class I, class II, and class III. Class I devices are simple products that usually present minimal potential for harm to the patient.[9] These devices are subject to "general controls," a set of controls applicable to virtually all devices, and which involve the least amount of regulation by FDA. General controls include labeling, provisions against adulteration and misbranding, good manufacturing practices ("GMPs"), establishment registration, medical device listing, and premarket notification prior to marketing a device, among others.[10] FDA has since exempted most class I devices from section 510(k) requirements of the Act pursuant to the authority provided by 21 U.S.C. § 360c(d)(2)(A).

22. In general, class II devices present a greater level of potential risk than class I devices. In addition to general controls, class II devices may be subject to additional special controls to provide a "reasonable assurance" of safety and effectiveness.[11] Special controls may include special labeling requirements, mandatory performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (such as for providing clinical data in 510(k) submissions), recommendations, and any other actions that the Secretary of Health and Human Services determines are necessary to provide a reasonable assurance of safety and effectiveness.

23. Under the Act, class III devices are those devices purported or represented to support or sustain human life, to be of substantial importance in preventing impairment of human health, or to present a potential unreasonable risk of illness or injury to patients.[12] Class III devices are therefore subject to the highest levels of FDA's regulatory controls, including general controls

8 21 U.S.C. § 301 *et seq*.
9 21 U.S.C. § 360c(a)(1)(A).
10 21 U.S.C. §§ 351, 352, 360, 360f, 360h, 360i, and 360j.
11 21 U.S.C. § 360c(a)(1)(B).
12 21 U.S.C. § 360c (a)(1)(C)(ii).

and any relevant special controls, and must undergo a rigorous FDA review process called premarket approval.[13] Independent of the statutory criteria for regulating a device in class III, all new devices are class III by operation of law unless FDA has classified them into class I or class II, or has determined the new device to be substantially equivalent ("SE") to a device previously classified in class I or class II by regulation or through the 510(k) process.[14]

24. FDA regulation of devices provides a "reasonable assurance of safety and effectiveness." What constitutes a reasonable assurance of safety is described in 21 C.F.R. § 860.7(d)(1) as follows:

> "There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use."

25. What constitutes a reasonable assurance of effectiveness is described in 21 C.F.R. § 860.7(e)(1) as follows:

> "There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results."

26. In assuring safety and effectiveness of devices, FDA is required to consider four factors: (1) the persons for whom the device is represented or intended, (2) the conditions of use for the device, (3) the probable benefits versus probable risks, and (4) the reliability of the device.[15]

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[13] 21 U.S.C. § 360e.
[14] 21 U.S.C. § 360c(f).
[15] 21 C.F.R. § 860.7(b)(1)-(4).

27. The 510(k) process is the means by which the vast majority of new devices are classified by FDA, thereby receiving FDA premarket authorization. For new devices that are determined to be substantially equivalent ("SE") to legally marketed devices, the 510(k) process is the least burdensome means for a company to receive FDA authorization to market its device in the U.S. Following 510(k) clearance, a company that is commercially distributing the class I or II device must comply with all relevant regulatory controls applicable to the classification for its device to be safe and effective. For companies commercially distributing class III devices, compliance with premarket approval requirements involves an actual demonstration of safety and effectiveness and conformance with all relevant regulatory controls.

A. The Premarket Notification ("510(k)") Process

28. At least 90 days before marketing a class I or II device in the United States for the first time, a manufacturer must notify FDA of its intent to introduce the product into interstate commerce by submitting a 510(k) submission, unless specifically exempted from this requirement.[16]

29. The purpose of a 510(k) submission is to demonstrate that a medical device is substantially equivalent ("SE") to a predicate device, which is basically a legally marketed class I or class II device. A medical device is determined to be SE to a predicate device if: (1) it has the same intended use as the predicate device; and (2) it has the same technological characteristics as the predicate device; or (3) it has different technological characteristics which do not raise new questions of safety and effectiveness and is shown to be "as safe and effective" as the predicate device.[17] If the device is determined by FDA to be not-substantially equivalent ("NSE"), the device is automatically placed into class III and is subject to PMA requirements unless the device undergoes a reclassification through one of several possible statutory means. FDA's determination of substantial equivalence is commonly referred to as a "clearance."

[16] 21 U.S.C. § 360k.
[17] 21 U.S.C. § 360c(i); 21 C.F.R. § 807.100(b).

30. Understanding the regulatory concept of intended use is essential for understanding the regulation of medical devices in the United States. The concept of intended use not only determines whether a product is regulated by FDA, in the case of a device, it influences the device's regulatory classification, as well as the path to market, as only devices having the same intended use as the predicate can be found SE. Changes in intended use are the bases for enforcement actions in the post-market period. The concept of intended use is defined by regulation in 21 C.F.R. § 801.4, and is discussed below in section III.E.

31. In assessing substantial equivalence, the concept of intended use is constrained with FDA being required to determine the intended use of a new device from the proposed labeling in the 510(k).[18] Promotion of an off-label use is prohibited and can result in charges of adulteration and misbranding.

32. For 510(k) submissions, sufficient information must be provided to permit FDA to conclude that the new device is "as safe and effective" as the device to which it is compared (*i.e.*, the predicate device). Such information includes the content requirements of 21 C.F.R. § 807.87, requiring among other things: the device name and class; an indications for use statement; a 510(k) summary; truthful and accurate statement; proposed labeling; a substantial equivalence comparison with a legally marketed predicate device(s); and, in certain instances, supporting performance data. For new devices having the same intended use and technological characteristics as a predicate device, substantial equivalence is often demonstrated with descriptive data alone. When questions arise regarding aspects of intended use, or differing technological characteristics, in relation to a predicate device, performance data is often required to demonstrate substantial equivalence. Under some circumstances, the required performance data may be clinical data, necessitating a clinical trial which may involve an investigational device exemption ("IDE") application.

[18] 21 U.S.C. § 360c(i)(1)(E).

33. A finding of substantial equivalence does not establish compliance with any general controls, other than section 510(k) of the Act. This is why FDA orders, i.e., letters, announcing an Agency finding that a new device to be SE to a legally marketed predicate device include language that explicitly states the legal and regulatory limits of substantial equivalence determinations and reinforces the requirement that the recipient comply with all applicable FDA requirements. This also differentiates the 510(k) process from the PMA process, where compliance with other regulatory requirements is verified by FDA. Furthermore, it contributes to the lower costs that are associated with navigating the 510(k) process.

34. There is tremendous variation in the time and expense associated with receiving substantial equivalence determinations, with the time and effort being dependent on the indications for use and the technological characteristics associated with the new device. The closer the indications for use and technological characteristics are between the new device and a legally marketed predicate device, the less time and effort it takes for a new device to be determined to be SE. When there are pronounced differences between the indications for use and technological characteristics of a new device and a legally marketed predicate device, it generally takes more time and effort for the new device to be evaluated and possibly determined to be SE. In some cases, differences between new and predicate devices may actually preclude substantial equivalence determinations. When FDA determines that substantial equivalence is precluded by the facts, 510(k) submitters face tremendous uncertainty regarding the appropriate regulatory pathway to market, as well as the specific premarket requirements.

35. The majority of 510(k) submissions are referred to as "traditional" 510(k)s, i.e., they stand on their own without the benefit of leveraging FDA recognized consensus standards, pertinent FDA guidance documents, or compliance with the design control provisions of the Quality Systems Regulation.[19] Traditional 510(k)s are subject to a 90-day FDA review. The time

[19] 21 C.F.R. § 820.30.

to completion of the review, however, is often extended because FDA requires additional information.

36. Under specific and limited circumstances, some devices may be the subject to what is referred to as an "abbreviated" or a "special" 510(k) submission. Regardless of whether a 510(k) is a traditional, abbreviated, or special, the submission must meet the content requirements of 21 C.F.R. § 807.87. For specific reasons that are largely administrative in nature, "abbreviated" and "special" 510(k) submissions may undergo a more streamlined FDA review leading to a faster clearance. However, new devices that are not the result of changes made by a 510(k) "holder' to its own legally marketed device are not eligible for review as a "special" 510(k) submission and, therefore, are automatically ineligible for FDA's self-imposed goal of completing the review within a 30-day review period.

37. It is important to understand that the submission of a 510(k) is not an acknowledgement that the subject of the submission is a device or that a 510(k) is required. Likewise, FDA acceptance of a 510(k) for review is not an affirmation that the subject of the 510(k) submission is a device or that the submission is required. FDA's final decision determines whether the product is a device and, if it is, its regulatory classification. An integral part of the review process that can lead to confusion relates to FDA requests for additional information. Part of the boilerplate language embedded in all written requests for additional information is a statement that informs submitters that they cannot market "the device" without an order finding the device to be substantially equivalent. In some cases, the FDA final decision reveals that the subject of the 510(k) is not a device, is subject to enforcement discretion (i.e., not actively regulated), or is "exempt" from 510(k) requirements. In other cases, FDA finds it to be more expeditious to simply clear the device for marketing although a 510(k) was not actually required. These decisions negate the legitimacy of the boilerplate statement appearing in additional information requests.

38. The issue of changes or modifications that 510(k) "holders" make to their legally marketed devices and which ones require FDA premarket authorization is a particularly complex

subject. The use of the words "significant changes", "could significantly affect", and "major change or modification" in the governing regulation (21 CFR § 807.81(a)(3)) result in substantial ambiguity. Although FDA has provided guidance to industry and FDA staff in this regard, it is not unusual for differences of opinion to exist between FDA and company employees regarding whether a particular change or modification requires a new 510(k) clearance. It is critical to understand that a 510(k) clearance for a change or modification to a legally marketed device is not evidence that a 510(k) was required. Too often differences of opinion or disputes are simply avoided by filing unnecessary 510(k) submissions. To illustrate the point, in some cases an FDA employee may verbally request that a 510(k) be submitted for a particular change and a company may voluntarily submit one to be later found SE. In other cases, FDA may issue a written request for a 510(k) submission for a change which results in a 510(k) clearance when the request for the 510(k) could have been overturned on closer examination or appeal.

39. Lastly, an FDA finding of substantial equivalence allows the 510(k) submitter to commercially distribute the device as described in submission, as long as the submitter conforms with all applicable general and special controls, such as 21 CFR § 801 - Labeling and 21 CFR § 820 – Quality System Regulation. Given that the circumstances under which the device is "manufactured" and the details of how the device is commercially distributed (i.e., packaged, labeled and provided to users), can affect its regulatory status, under limited circumstances it can appear that the submitter may be illegally distributing the device. Likewise, a denial of a clearance does not mean that there are no legitimate ways to commercially distribute the device in the U.S. To illustrate my point, a 510(k) clearance may be granted, subject to applicable general and special controls or be denied (found "NSE"). The manufacturer may decide that the registration and listing and 510(k) requirements are too onerous and commercially distributes the device to veterinarians. While it may appear that the manufacturer is distributing the device (or a modified version) in disregard of FDA requirements, the fact is that the device when distributed solely for veterinary

purposes is exempt from establishment registration, listing and premarket notification.[20] The bottom line is that one should not presume that the existence of a 510(k) clearance, or a "denial" of one, does not rule out the existence of an alternative way to legally provide the device to customers that appears contrary to the outcome of the 510(k).[21]

B. Premarket Approval Process

40. Class III devices are devices determined to be not substantially equivalent ("NSE") through the 510(k) process or are otherwise purported to support or sustain human life, to be of substantial importance in preventing impairment of human health, or to present a potential unreasonable risk of illness or injury to patients.[22] Class III devices are subject to the PMA process, which requires submission of a PMA application to FDA seeking approval to market the device within the United States.[23]

41. PMA applications are subject to the requirements of 21 C.F.R. § 814 – Premarket Approval of Medical Devices. Like 510(k)s, PMA applications have specific content requirements. Unlike 510(k)s, PMA applications require very detailed information and must include documentation that shows conformance with the general controls, any applicable special controls, and a reasonable assurance of the device's safety and effectiveness.

42. The procedures that FDA must follow in the review of PMA applications are identified in 21 C.F.R. § 814.44. Given the complex scientific and regulatory issues usually involved with FDA's premarket evaluation of class III devices, PMA applications almost always require review by an interdisciplinary team of scientists. Since PMAs always contain clinical study data, these review teams routinely include clinicians and biostatisticians. For all first and many second-of-a-kind class III devices, PMAs are reviewed by an advisory panel made up of special government employees ("SGEs") that are experts from outside FDA that are free of conflict

[20] 21 CFR § 807.65(b)
[21] The term "denial" is used in the context of a not-substantially equivalent ("NSE") determination that results in the submitter of the 510(k) not being granted FDA premarket authorization for the subject device.
[22] 21 U.S.C. § 360c(a)(1)(C)(ii).
[23] 21 U.S.C. § 360e.

of interest. Once FDA determines that advisory panel input is not needed for a type of class III device, future PMAs may not be taken before an advisory panel for review. Similar to 510(k) submissions, once all FDA reviews are complete, they are used to support a decision to approve, deny, or request additional information. The statutorily mandated review time for PMAs is 180 days. As with 510(k)s, FDA frequently requests additional information during the review period which often extends the review period beyond 180 days.

43. The requirements for approval of a PMA are provided at 21 C.F.R. § 860.7 and 21 C.F.R. § 814. Sections 860.7(c) and (d)(1) & (e)(1) require that approval be based on "valid scientific evidence" that the device is safe and effective, and that it will provide clinically significant results. Valid scientific evidence is linked to investigational device exemptions ("IDE") requirements. To establish the safety and effectiveness of a device sufficient to support approval of a PMA application, the applicant must submit data from one or more well-controlled clinical studies.[24] Prior to conducting studies in the U.S. involving a significant risk device, the applicant must prepare an IDE application and submit it to FDA seeking approval of its proposed study, and FDA must approve the study before it is initiated. The IDE application permits a device that is not approved or cleared for marketing to be shipped in commerce for the purpose of conducting clinical studies to support premarket authorization.[25]

C. Evaluation of Automatic Class III Designation (De Novo Classification)

44. The Food and Drug Administration Modernization Act of 1997 ("FDAMA") created an alternative to a PMA application for a subset of medical devices that are in class III by virtue of a NSE determination, or the lack of predicate device. The alternative, known as "Evaluation of Automatic Class III Designation" is more commonly referred to as "*de novo* classification," with the route to market known as a "*de novo* request."

[24] 21 C.F.R. § 360c(a)(3)(A).
[25] 21 U.S.C. § 360j(g)(2); 21 C.F.R. § 812.1(a).

45. *De novo* classification allows eligible devices that do not have a predicate device or are NSE to be legally marketed. *De novo* requests do not demand the scientific rigor of premarket approval to be classified in class I or class II. The burden of justifying lesser regulation rests on the submitter and requires that the submitter demonstrate that a reasonable assurance of safety and effectiveness will be achieved through adherence to general controls or a combination of general and special controls. While this may appear straightforward, there are no objective criteria that the agency employs to assess the adequacy of general and special controls to assure safety and effectiveness, creating significant uncertainty. Unless FDA is encouraging the submission of a *de novo* request following a NSE decision, success is difficult to predict.

46. The *de novo* request process is described in an FDA guidance document entitled "De Novo Classification Process (Evaluation of Automatic Class III Designation)" dated October 30, 2017. Under current law, FDA's goal is to make decisions regarding *de novo* requests in 150 review days, which may be extended when additional information is requested by the agency. Because of the relatively small number of *de novo* requests that are submitted annually and the diversity of devices that are the subjects of the requests, coupled with the variability in FDA's historical performance in meeting the target timeline, it is impossible to predict with any certainty how long it may take to receive a favorable FDA *de novo* decision.

47. All devices that reach the market through the *de novo* process may be used as predicates for future 510(k) submissions, making the burden for the first company to reach the market through the process much higher than any that follow. While a *de novo* request is less onerous than a PMA, it is substantially more difficult to navigate than the 510(k) process and involves great uncertainty.

D. Intended Use

48. The foundation for FDA regulation of devices rests largely on the regulatory concept referred to as "intended use." For devices, the meaning of "intended uses" appears in 21 C.F.R. § 801.4 as follows:

> "The words *intended uses* or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for a device approved, cleared, granted marketing authorization, or exempted from premarket notification based solely on that firm's knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses."

49. For class I and II devices and the review of 510(k) submissions, section 513(i)(1)(E) of the FDCA generally limits the determination of the intended use of a subject device to the proposed labeling contained in the 510(k) submission. Evidence of intended use outside of proposed labeling may be considered; however, the statute limits FDA's actions during premarket review to when "there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device" and "that such use could cause harm."[26]

[26] *See* Section 513(i)(1)(E)(ii) of the FDCA.

50. When reviewing proposed labeling, intended use is determined from the indications for use, any contraindications, warnings, and precautions, as well as the instructions and conditions for use in the labeling. However, intended use is mostly associated with the indications for use statement. In February 6, 1996, while I was the Deputy Director of FDA's Office of Device Evaluation, I implemented a policy that requires the indications for use statement to accompany every order issued by FDA finding a new device to be SE. The policy remains in effect to this day.

51. While the focus of determining a device's intended use tends to be on the indications for use statement, intended use encompasses much more than the indications for use. In fact, as defined in 21 CFR § 801.4, the concept of intended use is based on a person's "objective intent" which is essentially unconstrained. In the context of FDA enforcement actions that are based on a person's "objective intent," this provides the Agency with tremendous latitude in what actions it finds objectionable, however, because 510(k) filing requirements often hinge on whether a particular change constitutes a "major change or modification in the intended use of a device"[27], FDA developed guidance to industry to assist in determining what changes to intended use trigger the requirement to file a new 510(k).[28] In this regard, FDA ignored the complexity of what evidence establishes a person's objective intent, and focused exclusively on changes or modifications that manufacturers or distributors make to device labeling that may constitute a change that significantly affects the device's safety and effectiveness, therefore requiring a 510(k) clearance. The scope of this FDA guidance document is restricted to 510(k) clearance holders and changes that they make to their devices and not to device users or third parties.

52. Off-label use of a device involves any use that is unintended by the manufacturer or distributor and for which the device has not been cleared or approved by FDA. Most often, off-label use of a device is evident when the use is inconsistent with the FDA authorized indications

[27] 21 CFR § 807.81(a)(3)(ii)

[28] "Remanufacturing of Medical Devices -- Draft Guidance for Industry and Food and Drug Administration Staff" (published by the FDA on June 24, 2021, is available at https://www fda.gov/media/150141/download) (hereafter "Remanufacturing - Draft Guidance").

for use statement, however, off-label use encompasses all uses that are inconsistent with the device's labeling. In regard to off-label use, the Agency's position is that:

> **"Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment.** If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. (emphasis added)"[29]

53. Off-label use of a device, which is part of the "practice of medicine," is not a violation of the FDCA. In fact, the FDCA prohibits the agency from interfering with the practice of medicine.[30] When an off-label use requires a device modification, licensed practitioners are permitted to alter devices for use in their practice unfettered by regulatory requirements.[31] Additionally, licensed practitioners may have an original equipment manufacturer ("OEM") or a third party perform the alterations. FDA's authority in regard to off-label use is primarily limited to activities related to the sale and distribution of devices, to include labeling, as well as promotion and advertising activities.

54. Off-label "promotion" of devices is prohibited by law and can result in a misbranding charge. What constitutes off-label promotion, however, is not always obvious. For example, when a device is cleared for use in "monitoring" a patient but is promoted for use in "diagnosis" of a disease or condition, off-label promotion is obvious. Likewise, when a device approved by FDA for use in cardiology is promoted for use in orthopedics, off-label promotion is apparent. On the other hand, when a device bears a general indications for use statement, what constitutes off-label use and promotion is less clear. In fact, it is often impossible to predict what FDA may determine to be off-label versus on-label or, as I often say, "within-label."

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[29] U.S. Food and Drug Administration, "'Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices" (1998), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices.

[30] 21 U.S.C. § 396.

[31] 21 CFR § 807.65(d)

55. It is noteworthy that in defining intended use, FDA addresses the situation where "… a packer, distributor, or seller intends an article [device] for different uses than those intended by the person from whom he or she received the article" and takes the position that the "… packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses." The example involves entities in the distribution chain and does not include entities making changes at the request of a purchaser or user.

E. FDA Regulatory Landscape for Device Remanufactures

56. As of October 7, 1996 (the effective date of the Quality System Regulation), the term "remanufacturer" is defined as "… any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." [21 CFR § 820.3(w)]

57. Prior to the effective date and until December 4, 1998 (the date that FDA announced revocation of CPG 7124.28),[32] ownership of used devices was central to determining the regulatory responsibilities of ''reconditioners'' or ''rebuilders'' that restore or refurbish devices to the OEM's original or current specifications, or new specifications. If a reconditioner or rebuilder did not acquire ownership of the used device for the purpose of reselling the device, CPG 7124.28 did not state that this sort of reconditioner / rebuilder would be subject to registration, listing, premarket notification and other specified statutory and regulatory requirements.

58. Because of conflicts between the QSR and the CPG, and the fact that the CPG no longer reflected FDA thinking at the time, on December 4, 1998 FDA revoked CPG 7124.28. In doing so, the Agency reiterated its intent, as first expressed in an advance notice of proposed rulemaking (ANPR)[33], "… to consider identifying the used device market, for regulatory purposes, in terms of "refurbishers," "as-is remarketers," and "servicers" whose activities do not significantly change the safety, performance, or use of a device, and to examine alternative

[32] FDA issued CPG 7124.28, Reconditioners/Rebuilders of Medical Devices, on December 29, 1987. The document reflected FDA's views and practices that were in effect prior to issuance.

[33] 62 Fed. Reg. 67011 Cite the December 23, 1997, Federal Register

approaches for regulating these firms." In revoking the CPG, FDA did so contemplating "… the issuance of a rule or guidance setting forth FDA's current position …"

59. To date, FDA has not promulgated a regulation pertaining to the "used device market" and no guidance document outlining the Agency's thinking on the matter is in effect.[34]

F. Uncertainty Regarding 510(k) Requirements

60. The lack of a regulation or guidance document that addresses the regulatory responsibilities of "refurbishers," "as-is remarketers," and "servicers" of used devices, since the FDA revocation of the CPG 7124.28 in 1998, creates tremendous uncertainty regarding what FDA regulatory requirements these entities must meet, if any, but also the future of the used device market.

61. Only entities that are required to register their establishments with FDA are required to submit 510(k)s.[35] Because FDA has stated that "reconditioners/rebuilders" are specifically excluded from the definition of ''manufacturer'' or ''remanufacturer'' in the QS regulation, and "refurbishers," "as-is remarketers," and "servicers" are not mentioned in section 21 CFR § 807.20 Who must register and submit a device list, the applicability of the requirements to register establishments and list devices is ambiguous at best. Furthermore, the requirements are clouded by the fact that the regulation explicitly states that anyone who "Reprocesses a **single use device** that has previously been used on a patient [emphasis added]" must register and list. This is particularly relevant in the context of "refurbishers," "as-is remarketers," and "servicers" because the statement was added to the regulation as a result of Congressional action, specifically enactment of the Medical Device User Fee and Modernization Act of 2002 ("MDUFMA"), which altered the Agency's long-standing position that reprocessors of single use devices were basically unregulated. A similar Congressional action has not been taken and "refurbishers," "as-is remarketers," and "servicers" are not specified in 21 CFR § 807.20.

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[34] FDA issued a draft guidance entitled *Remanufacturing of Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff* on June 24, 2021. The draft guidance is labeled "Draft – Not for Implementation." Document available at https://www fda.gov/media/150141/download

[35] 21 CFR § 807.81(a)

62. Putting the ambiguity associated with registration and listing requirements aside, for companies that refurbish or service used devices that have no intent to significantly change the device's performance or safety specifications, but rather simply return the device to working order, can be reasonably confident that a 510(k) is not required. The real uncertainty relates to what constitutes a "significant change" and whether the company's actions are in alignment with its intent.

63. In the context of remanufacturing, to fully appreciate the difficulty in determining what constitutes a "significant change" one should consider the challenges that FDA and industry face when considering whether a change that an OEM makes to its own legally marketed device "could significantly affect the safety or effectiveness of the device" and require 510(k) clearance. In regard to this issue, I was one of three authors of FDA's guidance document for industry and FDA staff issued on January 10, 1997. It took years to develop the guidance document and put it in effect. While the guidance reduced industry /FDA conflict, reasonable people continued to disagree over whether a particular change "could significantly affect" device safety and effectiveness.

64. The 1997 guidance document, entitled *Deciding When to Submit a 510(k) for a Change to an Existing Device***,** has since been superseded by a revised guidance document bearing the same name, dated October 25, 2017. The revised guidance document did not implement any significant policy changes to FDA's current thinking on when the submission of a new 510(k) is required, but rather was intended to enhance "… the predictability, consistency, and transparency of the "when to submit" decision-making process..." As with its predecessor guidance document, reasonable people continue to disagree over whether some changes "could significantly affect" device safety and effectiveness.

65. The 2017 guidance document, as well as its predecessor guidance document, pertain to 21 CFR 807.81(a)(3) and changes that OEMs make to their own legally marketed devices and not 21 CFR 820.20(w) and what changes result in remanufacturing. The scope of the 2017 guidance document is particularly clear and states that it "… is not intended to address whether

submission of 510(k)s are required from remanufacturers of existing devices who do not hold the 510(k) for the device, such as reprocessors of single-use devices."

66. The relevance of these two guidance documents to the question of what changes to devices rise to a level of significance that constitutes "remanufacturing," lies in the fact that reasonable people disagree with what is "significant" and no amount of FDA guidance resolves all disagreement. Although there is no FDA guidance in effect on what constitutes a "significant change" and is therefore "remanufacturing," as is the case with OEMs making changes to their legally marketed devices, the responsibility for determining whether a particular change rises to a level of significance that requires the submission of a 510(k) rests with the person affecting the change. Once the modified device becomes available, it is up to FDA to disagree and require a 510(k). With an FDA guidance document in effect, there may be suggested ways of assessing significance, but without an FDA guidance document in effect, industry is left to interpret that regulations and do what seems reasonable.

G. Confusion Related to Intended Use

67. As addressed in paragraph 48, the concept of intended use is defined expansively in the context of overall FDA regulation, particularly in regard to Agency enforcement actions, however, it is defined much more generally in the context of 510(k) decision-making. In determining whether a device is SE to a legally marketed predicate device, FDA defines intended use as "the general purpose of the device or its function, and encompasses the indications for use."[36] This is a consequence of the fact section 510(k) is the predominant path to the U.S. market for new devices and that to be determined to be SE, a new device must have the same intended use as the predicate device with which it is compared.[37] A further consequence is that devices that differ in what may appear to be significant ways are considered by FDA to have the same intended use. To illustrate the point, it is common for a device intended for over-the-counter ("OTC") use

[36] FDA. Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for industry and Food and Drug Administration Staff. 10 Oct 2017. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

[37] 21 CFR § 807.100(b)(1)

to have the same "intended use" as a device intended for use by licensed health-care professionals ("prescription use"). Likewise, devices that are intended for single use always have the same intended use as the same types of devices intended for multi-use. To be more specific, a surgical instrument that is intended to be used for a maximum of 10 surgeries commonly has the same intended use as the same generic type of device intended to be used in an unspecified number of surgeries.

68. In the context of remanufacturing, the entity responsible for the "act"[38] affecting the finished device, whether new or used, has to significantly change the device's performance, safety, or intended use. In order for a change in intended use to be the basis for the "act" being considered "remanufacturing," the change would in all likelihood have to result in a use of the device in a different patient population or a different medical procedure, or for a different disease or condition. While it can be argued that many "acts" may "affect" intended use, the regulation requires that the act actually change the intended use in a significant way. The confusion that surrounds intended use is compounded by the lack of FDA guidance on what actual changes in intended use are "significant."

H. Uncertainty Related to FDA Regulation of Components

69. As discussed in paragraphs 17 and 18, components are devices as the term device is defined in section 201(h) of the FDCA. The term component is further defined in 21 CFR § 820.3(c) as "… any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device."

70. To understand how components are regulated by FDA, one needs to turn to 21 CFR § 807.20. As previously discussed in paragraph 61, 510(k)s are only required for persons that are required to register their device establishments with the Agency. In regard to component [and accessory] manufacturers, 21 CFR § 807.20(a) states that "The registration and listing requirements shall pertain to any person who is engaged in the manufacture, preparation,

[38] The term "act" is being used in the same context that it is used in 21 CFR § 820.20(w).

propagation, compounding, assembly, or processing of a device intended for human use, including any person who: … (6) Manufactures components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g. blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks."

71. To properly interpret the regulation, one needs to understand regulatory precedent. Devices are often extremely complex and are comprised of hundreds or thousands of individual components, from simple nuts and bolts to complex electrical circuits. The overwhelming majority of components are legally marketing in the U.S. without any FDA authorization, e.g., 510(k) clearance. Quite simply, this is because they are not packaged or labeled for commercial distribution for any health-related purpose. Their manufactures are not required to register their establishments with FDA and premarket notification (510(k) is not required. This does not mean that component manufacturers have no FDA regulatory responsibility. FDA's long-standing position has been that the exemption from establishment registration does not exempt component manufacturers from inspection under section 704 of the FDCA.[39]

72. There are component manufacturers that are subject to establishment registration requirements and section 510(k). The criteria for such rely on whether the specific component is packaged or labeled for commercial distribution for a health-related purpose for which it is intended to be used. The examples cited in 21 CFR § 807.20(a)(6) are illustrative. Blood filters and hemodialysis tubing are class II components of durable therapeutic devices that are packaged, labeled and shipped to healthcare facilities for individual use. Ophthalmic lens blanks are class I (510(k) exempt) components that are ground to a particular patient's prescription by opticians for use in spectacle frames. There are numerous other components that have been classified by FDA and comply with establishment registration and section 510(k) requirements.

[39] FDA. Compliance Policy Guide; **CPG Sec. 300.100 Inspection of Manufacturers of Device Components. Sep. 1987**. https://www fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-300100-inspection-manufacturers-device-components

73. In general, components that are not packaged, labeled and shipped to consumers or healthcare facilities are not subject to establishment registration and section 510(k) requirements.

74. An additional source of occasional confusion rests in differentiating "components" from "accessories." In 2017, FDA issued a guidance document pertaining to the regulation of accessories.[40] The guidance defines an accessory as a "… finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices." While the scope of the guidance is limited to accessories, it adopted and includes the definition of a component from the QSR. Yet, there is no discussion of components in the document. The fact is that the distinction between an accessory and a component may be non-existent. A class II wheel chair may be purchased with front and rear lights. The lights may appear to be components, i.e., a part intended to be included as part of the finished, packaged, and labeled device. On the other hand, lights could be accessories if viewed as finished devices intended to supplement and/or augment the performance of the wheelchair

IV. Foundation for My Opinions

75. The foundation upon which my opinions rest is built on my knowledge and 40+ years of experience in FDA regulation of devices, as well as my understanding of the activities in which SIS intended to engage related to Intuitive Surgical's EndoWrist instruments, along with Intuitive Surgical's alleged communications to customers in response to third party efforts to provide repair services for EndoWrist instruments. The SIS-related activities were determined by an interview with Mr. Greg Posdal, President and CEO of SIS, and my review of related materials, including the expert reports written by Heather S. Rosecrans (original and rebuttal), J. Lawrence Stevens, Dr. T. Kim Parnell, and Joshua S. Sharlin, Ph.D., which were produced to counsel for SIS during discovery in the above-identified lawsuit. Intuitive Surgical's alleged communications to customers was evaluated based upon SIS's statements in its Complaint filed in this case and statements SIS has made in filings presented to the Court.

[40] FDA. Medical Device Accessories – Describing Accessories and Classification Pathways Guidance for Industry and Food and Drug Administration Staff. 20 Dec. 2017. https://www.fda.gov/media/90647/download

A. Information from Interview with Greg Posdal on Friday, October 28, 2022

76. Mr. Posdal is the current President, CEO and owner of the company that his father formed in 1971.

77. SIS has been repairing devices since 1971; beginning with stainless steel instruments and expanding into flexible endoscopes and other miscellaneous devices that are found in healthcare facilities.

78. Mr. Posdal described his business as "medical equipment repair" and a lower cost alternative to hospitals returning product to original equipment manufacturers (OEM) for repair.

79. The majority of SIS's work is for hospitals and surgical centers, while over the years the company has done work for some manufacturers and, on occasion, for physicians.

80. The company is currently registered with FDA because it imports and distributes some new devices within the US. All devices that are listed with FDA are new devices being commercially distributed in the US for the first time. This is a small part of what SIS does today.

81. When asked whether all of the devices that are the subjects of servicing or repair are at the end of life, or at the end of life as defined by an OEM, Mr. Posdal indicated that, with the exception of Intuitive Surgical's EndoWrist instruments, none of the devices that SIS repairs or services have a "predetermined" end-of-life.

82. With respect to its servicing and repair operations, SIS does not take ownership of any devices, but rather accepts devices from hospitals and healthcare facilities and performs a service for a fee. There is a part of its business that receives used devices that are beyond repair where the company may take ownership and offer to provide a new device or a replacement device acquired on the open market. He indicated that this practice has nothing to do with Intuitive Surgical or the EndoWrist instruments.

83. All devices that are repaired or serviced by SIS are returned to customers from which they came. There is no batch processing after which devices are distributed to anyone other than the customer that sent each device to SIS for service or repair. Most devices are tracked by serial number, however, for the few stainless-steel instruments that do not have serial numbers,

SIS tracks them internally to ensure that each repaired or serviced device gets returned to the customer that sent it for repair or service.

84. In regard to the EndoWrist instruments, when asked what the company intended to do with a device sent for repair or service, Mr. Posdal indicated that SIS would examine the device, repair as needed, and return to the customer in the same working condition as originally provided by the OEM. Mr. Posdal indicated that some customers sent devices for repair or service that were functional and that SIS would simply inform the customer of the number of remaining lives and perform no additional service. In all cases, Mr. Posdal stated that SIS's intent was to provide each device that it received back to the customer in the same condition as Intuitive Surgical originally provided it, "To the extent you can."

85. Mr. Posdal stated that SIS intended for devices requiring servicing or repair to meet OEM specifications. He acknowledged that when a device is sharpened some small amount of material is removed. He stated his belief that OEM specifications for proper function are broad enough to encompass devices that have been sharpened multiple times. He indicated that in regard to sharpening, observing the "dip" through visual inspection is a valid means to determine if a sharpened device remains "suitable for use."

86. When asked whether SIS's customers provide specifications for devices, Mr. Posdal indicated that customers do not provide or set specifications, but rather defer to SIS render the device to be functional.

87. When asked how SIS's servicing compares to Intuitive Surgical's instructions for processing EndoWrist instruments between patients, he indicated that Intuitive Surgical's instructions are to clean and sterilize and visually inspect each device before releasing for use. Mr. Posdal stated that SIS receives devices for a reason, usually related to the device not functioning.

88. When asked where SIS gets replacement parts, e.g., cables, Mr. Posdal stated that Intuitive Surgical does not provide replacement parts. SIS is familiar with devices and device component parts and usually can acquire "off-the-shelf" components. Occasionally, SIS makes components, or purchases components fabricated by a machine shop. He stated that some

component's cannot or should not be replaced; citing an example of a crushed device or one that is "damaged beyond repair."

89. In regard to SIS performing the operation that resets the usage counter through the addition of a computer chip, Mr. Posdal indicated that SIS was shut down before any chips were actually inserted in the EndoWrist instruments sent to SIS for repair. He indicated that SIS was in the process of acquiring the usage counter reset chip when it was stopped and SIS did not perform the step of resetting the usage counter in any EndoWrist instruments.

90. When asked if Dr. T. Kim Parnell's description of the Interceptor board to reset the use counter is correct, Mr. Posdal indicated that it was and that an insertion of the Interceptor board provides users with an additional 10 lives. He further indicated that it was SIS' intent not to get outside of Intuitive Surgical's guidelines or Intuitive Surgical's established use parameters. He indicated that device functionality could have been validated well beyond 10 uses, but that SIS intended to provide customers with devices with 10 uses corresponding to what Intuitive Surgical had selected.

91. Mr. Posdal stated that SIS has operated under a Quality System for a while and that the company is in the process of getting ISO certification with hopes of having it by the end of the year. Mr. Posdal stated that he believed that SIS would have had ISO certification if it had not been stopped by Intuitive Surgical. He stated his belief that SIS' internal quality system is as good as the ISO standard. When asked how SIS' quality system compares to the QSR, he indicated that he would need to look at it and compare.

92. When asked about labeling, Mr. Posdal stated that most devices are returned to customers in a "poly bag" with some specialty instruments returned to customers in rigid containers for protection. He indicated that SIS does not provide labeling, such as package inserts or instructions for use similar to OEM labeling. He stated that invoices include device serial numbers that match serial numbers on the packages and advise customers to follow OEM instructions for use. That is what was planned for Intuitive Surgical's EndoWrist instruments.

B. Additional Relevant Details

93. SIS used Rebotix as an EndoWrist instrument repair sub-contractor and intended to become the exclusive repair service in the USA deploying Rebotix's interceptor chip technology for EndoWrist instrument repair.

94. SIS's EndoWrist instrument repair/service process employed and followed the procedures established by Rebotix. At the inception of its EndoWrist repair business SIS subcontracted its repair work to Rebotix. Because SIS has a long-standing direct relationship and strong reputation with hospitals, SIS also discussed (but never executed) a distributor agreement with Rebotix. Although SIS initially contracted EndoWrist repair to Rebotix Repair LLC, SIS had begun the process of setting up its own repair system at its facilities in Glendale Heights, Illinois, based on the existing Rebotix procedures. SIS's Response to Intuitive Surgical Interrogatory No. 5

95. This EndoWrist repair process included initial disassembly and inspection, checking the mechanical operation and integrity of all mechanical components, an electrical integrity check to confirm integrity of electrical insulation, cleaning, sharpening or alignment of the instrument tip, a series of tests to confirm that all the movements of the instrument tip are within original specifications, and setting the counter to a value corresponding to the initial setting of a new EndoWrist instrument. Id.

96. Based upon the inspection procedures carried out by SIS and/or Rebotix, in combination with observations made during such inspections with respect to surgical devices or instruments, including EndoWrist instruments, SIS believes that indications for use are not affected, and the surgical device or instrument is returned to its original safety and effectiveness. Further, SIS is not aware or in receipt of any complaints from any customer about a serviced or repaired surgical device or instrument's indication for use being affected, or any failure return the same to its original safety and effectiveness. SIS's Response to Intuitive Surgical Interrogatory No. 11.

97. Under this repair process, third parties such as Rebotix would be a supplier to SIS, which would have all client contracts and perform the majority of repairs. A meeting was held in February of 2020 at SIS's Glendale Heights facility regarding SIS's repair of EndoWrists. The meeting was attended by multiple representatives of a large hospital system having tens of millions in annual EndoWrist costs. The attendees at this meeting discussed SIS performing repair of EndoWrists as described above, i.e., with third parties such as Rebotix providing the updated chip and SIS performing the underlying repairs at its facilities. SIS's Response to Intuitive Surgical Interrogatory No. 5.

98. Intuitive Surgical's Instruments and Accessories User Manual identifies processes and parameters that are "recommendations" for the cleaning, disinfection and sterilization of instruments, accessories and endoscopes between uses. [Intuitive-00091261] In so doing, Intuitive Surgical contemplates that either a Central Sterile Supply Department (CSSD) or Sterile Processing Department (SPD) in healthcare facilities that routinely "… performs cleaning, sterilization **and other actions on medical devices and equipment** [emphasis added]" will perform the recommended processing procedures. [Intuitive-00091260]. In addition, the EndoWrist instrument's instructions for use recommend that users inspect instruments before use; specifically stating, "Before use, all instruments should be inspected for damage or irregularities. Do not use the instrument if damage or abnormalities are observed. Examples of damage include: broken cables, broken wires, scratches or cracks on the instrument shaft, broken, bent, or gouged instrument tips, cracked or broken pulleys near the instrument tips, cracks or missing pieces on the outer components surrounding the pulleys, loose tip or grips, or broken lever guards (if applicable)." [Intuitive-00000518] Within this context and with a clear understanding of proper EndoWrist instrument function, it is reasonable for SIS to have believed that its servicing activities would not significantly change EndoWrist instrument performance or safety specifications and that visual inspection would ensure this. It is also reasonable to believe that if routine use of the EndoWrist instrument could result in instrument damage or abnormalities that could affect the device's performance or safety specifications, and would be detected through inspection, that SIS

could visually inspect instruments after servicing to ensure that the device functions as Intuitive Surgical intended. Further, I am not sure what "other actions on medical devices and equipment" a CSSD and SPD may perform on a used EndoWrist instrument and what impact any deviations from Intuitive Surgical's "recommendations" may have on an instrument. Nevertheless, CSSDs and SPDs are in the same position as SIS, if they must ensure that they do not cause "…significantly changes the finished device's [EndoWrist instrument's] performance or safety specifications, or intended use" and become remanufacturers.

C. Information from SIS's Complaint and Court Filings

99. SIS asserts in its Complaint that Intuitive Surgical misleadingly told customers that SIS's services are contrary to FDA regulations. Specifically, SIS alleges in paragraphs 123-25 (emphasis added) of its Complaint against Intuitive that:

"123. Intuitive, in connection with the sale of its EndoWrist instruments, asserted false or misleading descriptions of facts or representations in its correspondence with its and SIS's customers and such misrepresentations were likely to cause consumer confusion or inaccurately describe the nature, characteristics, or qualities of its and SIS's commercial activities in violation of Section 43 of the Lanham Act, 15 U.S.C. § 1125.

124. Intuitive has at least misrepresented that SIS's services are contrary to FDA approvals of the EndoWrist products and are in violation of intellectual property rights. Intuitive sent such correspondence to multiple SIS's customers and potential customers. Intuitive made such statements knowingly, willfully, and/or recklessly that such statements were misleading. These misleading statements affected the purchasing decisions of such customers.

125. Intuitive's misrepresentations were made to SIS's customers, and upon information and belief, a significant number of Intuitive customers that have, or had, Intuitive Si robots."

Additionally, SIS asserts that Intuitive "made misleading statements that use of refurbished EndoWrists would violate FDA requirements". (Complaint ¶ 6). In particular, SIS states in its Complaint the following:

"97. A first set of Intuitive's misleading statements made by letter relates to FDA clearances. Couched in terms of "might prevent such products from performing" such that FDA and other regulations "may not apply," Intuitive states without any basis that "the hospital has no way to know whether the refurbished instrument meets the rigorous specifications" of Intuitive and the FDA. Intuitive also states that "any modification to allow for use of a da Vinci product beyond its useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use" in violation in 21 U.S.C. § 351.

98. The components of the EndoWrists are medical grade parts with a useful life of dozens if not hundreds of uses. They will operate within specification, particularly when properly inspected and repaired as is performed by SIS. Intuitive's allegation appears to be that use of EndoWrists beyond the counter limit is a violation of Intuitive's FDA clearances. Based on FDA clearances that have been identified for EndoWrists to date, this assertion is incorrect. At most, Intuitive merely mentions in its FDA applications that its devices have usage limits. Available 510(k) summaries are silent on usage limits, and have no prohibitions whatsoever on repair."

In further support of its Complaint about Intuitive Surgical's communications to customers, SIS points to Intuitive Surgical's letters to customers that say, for example, "the regulatory clearance provided to Intuitive by the FDA and other regulatory authorities may not apply to products that have been remanufactured or refurbished by unauthorized third parties" and "any modification to allow for use of a da Vinci product beyond its labeled useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use." SIS contends "Intuitive's statements accomplish Intuitive's purpose of implying that services from companies like SIS will cause customers to violate FDA regulation, to destroy SIS's business." Refer to Doc. 51, "PLAINTIFF SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS" at p.14.

V. Opinions and Supporting Analysis

It is my opinion that SIS acted reasonably in its effort to conform with all FDA medical device requirements. Any suggestion that the company, or its customers, were planning to engage in illegal activities is simply false and misleading. In particular:

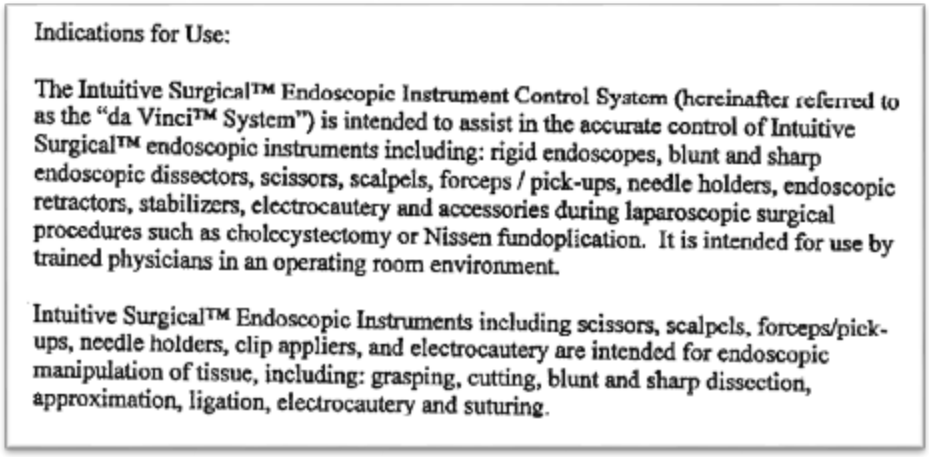
A. It was reasonable for SIS to conclude that its commercial activities did not constitute "remanufacturing" as the term is defined by the Quality System Regulation.

100. To be a "remanufacturer", SIS would have to be engaged in activities that "…significantly changes the finished device's ["EndoWrist instrument"] performance or safety specifications, or intended use." [21 CFR § 820.3(w)] Mr. Posdal indicated that SIS had no intent to do anything other than restore the performance of used EndoWrist instruments to the acceptable level of performance that is associated with Intuitive Surgical's performance specifications and intended use. I am aware of no evidence that suggests that SIS intended to engage in any activities that altered the performance of the used devices that it intended to service. In fact, Intuitive Surgical agrees that an entity cannot be a remanufacturer, under the FDA's definition, if it does not significantly change the device's safety specifications or intended use.

> Q. If a person or entity performs a process on a device that does not significantly change the finished device's performance or safety specifications or intended use, then that person or entity is not a remanufacturer; correct? THE WITNESS: Yes, by FDA's definition. -Johnson depo. tr., 108:20-109:1 (objection omitted).
>
> Q If Rebotix demonstrated that its services do not significantly change an EndoWrist performance for safety specifications or intended use, then Rebotix's would not be a remanufacturer, per the FDA's definition; correct? THE WITNESS: Yes. -Johnson depo. tr., 109:12-20 (objection omitted).

101. In regard to SIS significantly changing the EndoWrist instrument's intended use, Mr. Posdal stated that SIS did not intend to provide labeling for serviced devices. Without labeling the devices after servicing them, it is difficult to imagine how SIS could in any way alter the device's intended use.

102. Based on the contents of Intuitive Surgical's 510(k) submission, FDA classified Intuitive Surgical's device in class II, under 21 CFR § 876.1500 Endoscope and accessories, and cleared the EndoWrist instruments for entry to the U.S. market. Intuitive-00512045-00512407; Johnson depo. tr., 36:19-23. In its letter authorizing the marketing of the EndoWrist instruments, FDA portrayed the device's intended use in the following FDA authorized "Indications for Use" statement:



Indications for Use:

The Intuitive Surgical™ Endoscopic Instrument Control System (hereinafter referred to as the "da Vinci™ System") is intended to assist in the accurate control of Intuitive Surgical™ endoscopic instruments including: rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps / pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparoscopic surgical procedures such as cholecystectomy or Nissen fundoplication. It is intended for use by trained physicians in an operating room environment.

Intuitive Surgical™ Endoscopic Instruments including scissors, scalpels, forceps/pick-ups, needle holders, clip appliers, and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

103. Intuitive-00512047. Intuitive Surgical confirmed that the second paragraph quoted above pertains to Intuitive Surgical's EndoWrists. Johnson depo. tr., 37:22-39:17 Accordingly, both Intuitive Surgical and FDA advanced the key parts of the device's intended use through an indications for use statement that is the same as that used for traditional non-robotic surgical instruments used in endoscopic surgery. As FDA stated in the Indications for Use statement, the device includes a number of components:

i. "Intuitive Surgical Endoscopic Instruments [i.e., EndoWrists] including scissors, scalpels, forceps/pickups, needle holders, clip appliers, and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing." Intuitive-00512047.

104. There is no mention of a maximum use limitation in regard to any component part in the Indications for Use statement. This was confirmed by Mark Johnson, Intuitive Surgical's

Senior Vice President for Regulatory, who Intuitive designated to provide 30(b)(6) testimony on behalf of Intuitive Surgical:

> Q The Intended Use, as defined by Intuitive in this FDA submission, makes no mention of maximum use restrictions; correct? A Correct. -Johnson depo. tr., 30:25-31:3.
>
> Q Understood. Turning back to the Indications for Use Statement in the enclosure, the indications for use for EndoWrists adopted by the FDA does not reference any maximum use restrictions; correct? MS. LENT: Object to the form. THE WITNESS: Correct.
>
> Q The Indications for Use Statement references scissors; correct? A It does.
>
> Q The Indications for Use Statement does not state that scissors can be used a maximum number of 10 times; correct? A Correct.
>
> Q The Indications for Use Statement references scalpels; correct? A It does.
>
> Q Indications for Use Statement does not state that scalpels can be used a maximum of 10 times; correct? A It does not say that, no.
>
> Q The Indications for Use Statement does not put any limitations on the number of times that the scalpels, the scissors, the forceps, the needle holders, the clip appliers can be used; correct? A Correct. -Johnson depo. tr., 40:15-41:16.

105. Recently, for certain EndoWrist components, Intuitive Surgical changed the maximum use restrictions. In doing so, Intuitive Surgical addressed the question of whether extending the maximum use requirement (i.e., increasing the number of lives for an EndoWrist) constitutes a change in the EndoWrist's intended use.

106. Intuitive Surgical concluded that it does not. In its Non-Filing Justifications, Intuitive Surgical repeatedly wrote: "Extending the number of lives does not involve any changes to the intended use(s) or instrument design." Johnson depo., Ex. 14 (Non-Filing Justification) at Intuitive-00552635; Ex. 15 (Non-Filing Justification) at Intuitive-00552700 (same); Ex. 16 (Non-Filing Justification) at Intuitive-00552718 (same); Ex. 17 (Non-Filing Justification) at Intuitive-

00552729 (same); Ex. 18 (Non-Filing Justification) at Intuitive-00552654 (same); Ex. 19 (Non-Filing Justification) at Intuitive-00552666 (same).

107. Intuitive Surgical confirmed this conclusion at deposition:

> Q Intuitive concluded that extending the number of lives does not involve any changes to the intended use or instrument design; correct? A Correct. - Johnson depo, tr. 73:11-14.

108. The intended use of an EndoWrist is not significantly affected by an increase in the maximum number of uses specified for the EndoWrist.

109. I understand that opposing experts have taken the position that inserting an electronic circuit board to reset the EndoWrist instrument's use counter is a significant change in intended use and that this change alone could make SIS a remanufacturer. While experts may look at this specific issue differently, SIS' intent was to restore the EndoWrist instrument's useful life to the same number of uses chosen by Intuitive Surgical. Shortening, maintaining, or lengthening the number of permissible uses does not result in a "new" intended use.[41] Changes of this nature are routinely made by industry without filing 510(k)s and when they are the subjects of 510(k)s, they are routinely found SE [substantially equivalent]; establishing that changes of this nature do not result in a new or different intended use.

110. For certain EndoWrist instruments, Intuitive Surgical itself changed the "performance specifications" from "10 lives to 14 lives," from "10 lives to 15 lives," or from "10 lives to 18 lives." Johnson depo., Ex. 14 (Non-Filing Justification) at Intuitive-00552638; Ex. 16 (Non- Filing Justification) at Intuitive-00552720; Ex. 17 (Non-Filing Justification) at Intuitive-00552732. Despite making these changes, Intuitive Surgical concluded that it was not required to submit a 510(k) because "increasing the number of lives for these instruments is not expected to significantly affect the safety or effectiveness of the device." Johnson depo., Ex. 14 (Non-Filing

[41] Note: For manufactures with cleared 510(k)s, changes that impact the subject device's intended use may require FDA premarket authorization and the submission of a new 510(k). Under these circumstances, the submission of a 510(k) does not establish that the intended use has changed, however, an FDA clearance establishes that the intended use remains the same.

Justification) at Intuitive-00552638; Ex. 15 (Non-Filing Justification) at Intuitive-00552703 (same); Ex. 16 (Non-Filing Justification) at Intuitive-00552720 (same); Ex. 17 (Non-Filing Justification) at Intuitive-00552732 (same); Ex. 18 (Non-Filing Justification) at Intuitive-00552656 (same); Ex. 19 (Non-Filing Justification) at Intuitive-00552669 (same).

111. Given that Intuitive Surgical believed that resetting the usage counter to increase the number of instrument lives is not of a nature that "could significantly affect" device safety or effectiveness, it is reasonable for SIS to believe that its resetting the usage counter to increase the number of lives for the instrument does not significantly affect the safety or effectiveness of the EndoWrist, rendering it to be a remanufacturer subject to 510(k) requirements.

112. Rebotix has serviced almost 600 EndoWrists for U.S. hospitals, beginning in March 2019. REBOTIX165988; Sharlin Expert Report citing Feigel conversation. Dr. Sharlin states in his report that the evidence from the Rebotix case and his independent investigation show that none of these Rebotix-serviced EndoWrist instruments has resulted in an adverse event reported to FDA. For example, Dr. Sharlin searched the MAUDE database and discovered that there were 131 adverse event records involving EndoWrist devices since 2019 (the first year Rebotix serviced EndoWrists). None of the lengthy narrative descriptions of the 131 adverse events included any content about Rebotix or a refurbished device.

113. Sharpening surgical instruments, including scissors, is not a new practice. SIS has been in business for over 50 years and repairing stainless steel surgical instruments was one of the company's first endeavors. As Mr. Posdal indicated, sharpened instruments can be visually inspected for acceptable function, and while repeated sharpening removes material, visual inspection can ascertain whether the sharpening affects performance. There is no evidence that I have seen that the scissors used in the EndoWrist instruments cannot be sharpened like other endoscopic surgical instruments that SIS has successfully processed for years.

114. FDA's draft guidance document on remanufacturing is not in effect and FDA has never established procedures or a thought process by which "remanufacturing" can be distinguished from "servicing". While there has been considerable regulatory activity geared at

better understanding the used device market, FDA has done nothing that imposes regulatory requirements on self-identified "refurbishers," "as-is remarketers," and "servicers" of used medical devices.

B. SIS's decision to engage in its commercial activities without FDA authorization was reasonable. Any suggestion that a 510(k) was required for SIS to process Intuitive Surgical's EndoWrists, or that its customers would be violating FDA law by doing business with the company, is false and misleading.

115. Unless SIS's planned servicing activities constituted remanufacturing, there was and is no requirement that SIS register as a device establishment and list its devices. As previous established, only registered establishments are required to file 510(k)s and receive FDA premarket authorization.

116. In regard to any thought that SIS, or any other entity, was required to submit a 510(k) and receive FDA premarket authorization for the added circuit board that was intended to be inserted in the EndoWrist instrument to reset its use counter after servicing, the thought is incorrect. While I agree that the added circuit board is a "component" of the serviced device, the only relevance of it being a component pertains to its use by manufacturers and remanufacturers. Because SIS is neither, references in the QSR to what is defined as a "component" that becomes a part of a finished, packaged and labeled device has no relevance.[42] What is relevant is the fact that the manufacturer or distributor of the circuit board to reset the usage counter is not subject to establishment registration. In order for the registration requirements to apply, the usage counter reset circuit board would have to be manufactured and intended for immediate use in a health-related purpose and be "… packaged or labeled for commercial distribution for such health-related purpose …" As discussed in paragraph 70, a circuit board that is shipped to a service provider for incorporation into a device has no "health-related purpose" as illustrated by the examples cited in the regulation.[43] Furthermore, the circuit board would have to bear labeling in conformance with the labeling regulation. FDA's device labeling regulation, 21 CFR § 801, pertains to devices that

[42] Refer to 21 CFR §§ 820.3(c)
[43] Refer to 21 CFR §§ 807.20(a)(6) and 807.65(a)

are shipped to an ultimate consumer, i.e., a lay person (for "over-the-counter" devices) or a licensed healthcare provider/healthcare facility (for "prescription" devices). The usage counter reset circuit board that SIS intended to insert into a serviced EndoWrist instrument has no "health-related purpose" as illustrated in the regulation and I am not aware of any chip labeling that suggests that one could exist.

C. The submission of a 510(k) and an FDA clearance by others does not establish that either is in fact necessary or required for SIS's repair services.

117. Unnecessary 510(k)s are regularly submitted to FDA for a myriad of reasons.[44] It is well known that individuals and companies submit 510(k)s that are unnecessary and that FDA regularly finds the subjects of what may be unnecessary 510(k)s to be SE.

118. In accordance with 21 CFR § 807.100(b), the focus of a 510(k) review is always a device and how it compares to a legally marketed predicate device. The circumstances under which the device is created is not a consideration in whether it is SE to a predicate device. In fact, there is no requirement that manufacturing information be included in a 510(k) submission.[45]

119. I understand that Rebotix filed a 510(k) and withdrew it after receiving a request for additional information from FDA. Although the additional information request stated that the device that is the subject of the submission cannot be marketed until FDA finds it SE, as I established in paragraph 37 of this report, the statement is boilerplate language that the Agency always uses in additional information requests and it means nothing in the context of a device that does not require 510(k) clearance in order to be marketed.

120. On September 30, 2022, FDA cleared 510(k) number K210478 for Iconocare Health's "8mm Monopolar Curved Scissors." Based on the 510(k) Summary that is available on FDA's publicly available database[46], it is clear that Iconocare Health is engaged in a "reprocessing" activity involving Intuitive Surgical's Da Vinci S/Si EndoWrist Instruments and

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44 Phillips, PJ and Lynne, JC. 2005. Unnecessary 510(k) Filings: A Waste of FDA and Industry Resources. *Regulatory Affairs Journal (Devices)* 13:341-345.

45 21 CFR § 807.87

46 Available at https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf

Accessories[47], although details of the activity that were revealed to FDA in the 510(k) submission are unknown. The following FDA conclusion is very insightful and requires analysis:

> "The design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles are equivalent to the predicate device. The mechanism of action of the subject device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, or method of operation. The change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments."

121. First, it is obvious that Iconocare Health has extended the useful life of an Intuitive Surgical device beyond the 10-use limit imposed by Intuitive Surgical. Iconocare Health demonstrated to FDA's satisfaction that modifying and relabeling each "presumably used" Intuitive Surgical device to create a "new" device, with an additional 10 uses, is SE to the predicate devices. This clearly establishes that the "intended use" of the Intuitive Surgical's legally marketed EndoWrist device is the same as the intended use of Iconocare Health's newly cleared device. Second, it is clear that FDA considered the extension of the useful life of the 8mm Monopolar Curved Scissor Instruments by 10 uses as a change in "device specifications" and not a change in intended use. In this regard, even though the specifications are identical, it appears that Iconocare Health provided performance data to FDA that demonstrated that "... the reprocessed devices are as safe and effective as the predicate and operate as originally intended." Furthermore, the company convinced FDA that testing each individual device before release establishes the "… appropriate function of its components prior to packaging and labeling operations." It is not surprising that FDA determined the device to be SE as it is virtually identical to the predicate devices in all respects and one would anticipate that they are as safe and effective. The result of this SE determination is that FDA expects that Iconocare Health will fulfill all medical device

[47] Five Intuitive Surgical 510(k) clearances are identified as predicate devices, specifically, K180033, K050369, K081177, K123329, and K170644

requirements, including registration and listing as required by 21 § CFR 807, filing 510(k)s for future changes and modifications to the device as required by 21 CFR § 807.81(a)(3), properly labeling their devices for commercial distribution as required by 21 CFR § 801 and meeting quality system requirements in accordance with 21 CFR § 820. In its 510(k) summary, FDA did not refer to Iconocare Health as a "remanufacture", but rather as a "reprocessor." On the basis of the information that is publicly available, it is not obvious that FDA made a legal or regulatory decision that Iconocare Health's activities constituted "remanufacturing" and that a 510(k) was required. Furthermore, there is no reason to believe that this 510(k) clearance has any relevance to SIS' situation except in one respect; SIS cannot remanufacture, relabel and repackage Intuitive Surgical EndoWrist instruments and commercially distribute them on the open market under its own name. Iconocare Health can do so. The regulatory status of any other activities undertaken by Iconocare Health are uncertain.

122. In December 2021, Intuitive Surgical submitted a 510(k) for changes to the da Vinci X/Xi 8mm Reusable Instruments to increase the number of lives (uses) and reprocessing cycles. [Intuitive 02053646] Intuitive Surgical had concluded that the change did not require FDA premarket authorization and the change had already been implemented with modified devices being placed in commercial distribution. According to Intuitive Surgical employee Thomas E. Claiborne, Ph.D., the 510(k) was submitted at the verbal request of an FDA employee with the understanding that the Agency would exercise "enforcement discretion," i.e., not take an enforcement action against the company for marketing an illegal device, while the 510(k) was under review. As discussed in paragraph 38, the submission of this 510(k) is not evidence that the change was of a nature that "could significantly affect safety and effectiveness" and required a 510(k) clearance. Based on the deposition of Dr. Claiborne, there was a disagreement between Intuitive Surgical and an FDA employee regarding the significance of the change and the 510(k) was submitted to avoid any conflict.

D. Intuitive Surgical's Customer Communications Alleged in SIS's Complaint and Court Filings Are Simply False and Misleading

123. As I express in the preceding sections of this report, in my opinion: (1) it was reasonable for SIS to conclude that its commercial activities did not constitute "remanufacturing" as the term is defined by the Quality System Regulation; (2) SIS's decision to engage in its commercial activities without FDA authorization was reasonable; and (3) the submission of a 510(k) and the existence of a FDA 510(k) clearance does not establish that either is in fact actually required.

124. As I state below, if SIS had consulted with me at the time it was setting up its "servicing" operation in regard to Intuitive Surgical's EndoWrists and asked whether the company was subject to active FDA regulation (specifically, registration and listing, premarket notification, and the quality system regulation), I would have advised SIS that it was not.

125. Consequently, it is my further opinion that Intuitive Surgical's communications to customers stating, suggesting or implying that SIS's services with respect to repair of EndoWrist instruments are contrary to FDA regulations and will cause customers to violate FDA regulations are objectively unreasonable. Indeed, to the extent a reasonable person would understand Intuitive Surgical's alleged communications to state, suggest or imply that the FDA has made an official determination that SIS's repair services for EndoWrist instruments violate FDA regulations unless a 510(k) clearance has been granted is false or at least highly misleading as to FDA's asserted authority over medical device repair services.

VI. Conclusion

If SIS had consulted with me at the time it was setting up its "servicing" operation in regard to Intuitive Surgical's EndoWrists and asked whether the company was subject to active FDA regulation (specifically, registration and listing, premarket notification/510(k) requirements, and the QSR), I would have advised SIS that it was not. Based on the information that I have reviewed in the context of this case and presented in this report, it is my opinion that SIS is not a

remanufacturer, as that term is defined by FDA, and that the company acted reasonably in its effort to conform with all applicable FDA medical device requirements. Furthermore, any suggestion that SIS's planned commercial activities, with respect to Intuitive Surgical's EndoWrist instruments, are contrary to the FDCA and will cause customers to violate the law, is false and misleading.

If called upon to testify at trial, I expect to prepare additional demonstrative materials reflecting the opinions set forth in my report.

Executed on December 2, 2022

_____

Philip J. Phillips

Exhibit 1

Bates-Stamped Documents

- Intuitive-00000501
- Intuitive-00000518
- Intuitive-00091257
- Intuitive-00091260
- Intuitive-00091261
- Intuitive-00202493
- Intuitive-00512045-00512407
- Intuitive-00552635
- Intuitive-00552638
- Intuitive-00552654
- Intuitive-00552656
- Intuitive-00552666
- Intuitive-00552669
- Intuitive-00552700
- Intuitive-00552703
- Intuitive-00552718
- Intuitive-00552720
- Intuitive-00552729
- Intuitive-00552732
- Intuitive-02053646
- Intuitive-02070398
- Intuitive-00208694
- Intuitive-00212457
- Intuitive-00510727
- Intuitive-00676719
- Intuitive-00841519
- Intuitive-00968032
- Intuitive-01098532
- REBOTIX124432-REBOTIX124447
- REBOTIX124467-REBOTIX124705
- REBOTIX124718-REBOTIX124756
- REBOTIX165988

Case Documents

- ECF Dkt. 1, SIS's Complaint, May 10, 2021
- ECF Dkt. 51, SIS's Opposition to Defendant's Motion to Dismiss, August 20, 2021
- SIS Response to Intuitive Interrogatory No. 5
- SIS Response to Intuitive Interrogatory No. 11

Depositions

- Mark Johnson 30(b)(6) Deposition Transcript and Exhibits, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, June 4, 2021
- Ted Clairborne Deposition Transcript and Exhibits, *Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC, November 21, 2022

Expert Reports

- Expert Report written by Heather S. Rosecrans, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, July 26, 2021
- Expert Rebuttal Report written by Heather S. Rosecrans *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021
- Expert Report written by J. Lawrence Stevens, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021
- Expert Report written by Dr. T. Kim Parnell, *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, August 30, 2021
- Expert Report written by Joshua S. Sharlin, Ph.D., *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-cv-02274, July 25, 2021

Literature

- Phillips, PJ and Lynne, JC. "Unnecessary 510(k) Filings: A Waste of FDA and Industry Resources. Regulatory Affairs Journal (Devices)" (2005): 13:341-345

Other

- Interview with Mr. Greg Posdal, President & CEO of SIS
- Product Code "NAY" - System, Surgical, Computer Controlled Instrument

Publicly Available Documents

- U.S. Food and Drug Administration, "Remanufacturing of Medical Devices -- Draft Guidance for Industry and Food and Drug Administration Staff", June 24, 2021, https://www.fda.gov/media/150141/download
- U.S. Food and Drug Administration, "Medical Device Accessories – Describing Accessories and Classification Pathways Guidance for Industry and Food and Drug Administration Staff", December 20, 2017, https://www.fda.gov/media/90647/download
- U.S. Food and Drug Administration, CPG 7124.28, December 29, 1987
- Federal Register Vol. 62, No.246, December 23, 1997
- 510(k) Summary of K210478, https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf
- K180033, K050369, K081177, K123329, and K170644 Intuitive Surgical 510(k) clearances

Websites

- U.S. Food and Drug Administration, "'Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices" (1998), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices
- U.S. Food and Drug Administration, "Deciding When to Submit a 510(k) for a Change to an Existing Device Guidance for industry and Food and Drug Administration Staff.' (October 10, 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device
- U.S. Food and Drug Administration, "Compliance Policy Guide; CPG Sec. 300.100 Inspection of Manufacturers of Device Components" (September 1987), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-300100-inspection-manufacturers-device-components

Exhibit 2

PHILIP J. PHILLIPS
EXPERT WITNESS LOG

*** * ***

FOR EXTERNAL DISTRIBUTION

*** * ***

Updated November, 2022

I. U.S. PROCEEDINGS

Depositions and/or Testimony

1. 2021—Fortis Advisors LLC, v. Allergan W. C. Holdings Inc.
Case No. 2019-0159-MYZ
[Deposition via Webex, Washington, D.C. June 28, 2021]

2. 2020—G. Patrick Maxwell. v. Lifecell Corporation and Allergan PLC.
JAMS Ref. No. 1425029058
[Trial via Webex, New York, NY., December 17, 2020]

3. 2020—G. Patrick Maxwell. v. Lifecell Corporation and Allergan PLC.
JAMS Ref. No. 1425029058
[Deposition, Washington, D.C., October 28, 2020]

4. 2019—Channel Medsystems, Inc. v. Boston Scientific Corporation
Case No. 2018-0673-AGB
[Deposition, Washington, D.C., March 26, 2019]

5. 2017—Bahamas Surgery Center, LLC v. Kimberly-Clarke Corporation and Halyard Health, Inc.
Case No. 2:14-cv-08390-DMG-PLA (US District Court for the Central District of CA)
[Trial, Los Angeles, California, April 4, 2017]

II. EUROPEAN PROCEEDINGS

III. FACT WITNESS TESTIMONY

Exhibit 3

PHILLIPS CONSULTING GROUP, LLC

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Silver Spring, MD 20908
Telephone – 202-420-9042

RESUME

Philip J. Phillips

EDUCATION

1982	MBA, George Washington University, School of Government and Business Administration, Washington, DC
1976	BS, Microbiology, University of Maryland College Park, MD

EXPERIENCE

Current

President
PHILLIPS CONSULTING GROUP, LLC
P. O. Box 12129
Silver Spring, Maryland 20908

Philip J. Phillips is President **PHILLIPS CONSULTING GROUP, LLC.** The firm provides strategic scientific and regulatory consulting services to clients and their counsel on public health related issues, with a focus on managing the most challenging issues in regulatory, public policy, and litigation forums. Mr. Phillips has 41 years of experience in FDA regulation of medical devices, having focused on the development and implementation of numerous regulatory strategies regarding the design, manufacture and distribution of medical devices and combination products in the United States. He brings an in-depth knowledge of a wide range of regulatory matters, including FDA jurisdiction and compliance, device classification and premarket review, clinical trials, human subject protection, product labeling, promotion and advertising, and post-marketing surveillance. His device experience crosses all medical specialties, including *in vitro* diagnostic devices.

Previous Positions

2005-2009 Executive Vice President and
Director, Medical Device Practice
Becker & Associates Consulting, Inc.
Washington, D.C.

Becker & Associates Consulting was a Washington, D.C.- based consulting firm that focused on the needs of FDA regulated industry. As the Executive Vice President and Director of the Medical Device Practice, Mr. Phillips managed the day-to-day demands of the practice by ensuring that the firm's healthcare clients and their counsel received sound strategic scientific and regulatory advice. Mr. Phillips used his business background and his 24 years of experience in FDA regulation of medical devices to develop and implement numerous successful regulatory strategies to achieve FDA authorization to distribute innovative medical devices in the United States while maintaining compliance with FDA requirements. Mr. Phillips' in-depth knowledge of allowed the firm to expand services to all medical device sectors, including *in vitro* diagnostic industry.

1994-2005 Deputy Director, Science and Regulatory Policy
Office of Device Evaluation
United States Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland

The Office of Device Evaluation (ODE) was the organizational unit in FDA that is responsible for the premarket evaluation of medical devices intended for commercial distribution in the United States.[1] ODE applied principles of sound science and exercised good regulatory judgment in the review of safety and effectiveness data and in granting medical device market authorizations. As the Office's chief scientist and administrator, Mr. Phillips planned, managed and directed all premarket review programs that ensure the safety and effectiveness of medical devices marketed and used in the United States. Mr. Phillips provided executive leadership in managing and directing six review divisions that encompassed all medical specialties, three support staffs, and a total work force of over 300 scientists, engineers and clinicians.

2003-2005 Acting Deputy Director, Office of Science and Engineering Laboratories
United States Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD

[1] As a result of a Center for Devices and Radiological Health reorganization in 2019, ODE was subsumed in a new organization that is referred to as the Office of Product Evaluation and Quality (OPEQ). All ODE functions are performed by OPEQ today. ODE review divisions have been realigned by medical specialty and converted to Offices of Health Technology bearing names with the medical specialties they represent.

The Office of Science and Engineering Laboratories (OSEL) performs product testing; develops reliable standardized test methods for government and industry use; performs anticipatory scientific investigations on emerging technologies; contributes laboratory data to national and international standards used in CDRH decision making; provides scientific and technical training for CDRH staff members; and maintains laboratory collaborations and relationships with scientific researchers in academia and other Federal laboratories. OSEL also coordinates and oversees CDRH's activities that support the development of national and international standards. Mr. Phillips integrated OSEL's laboratory scientists into ODE's premarket review programs, including a streamlined guidance development initiative for the Commissioner of Food and Drugs.

1987-1994 Director of Program Operations, ODE

1993-1993 Interim Director, Division of General and Restorative Devices, ODE

1986-1987 Acting Deputy Director, Division of Ophthalmic Devices, ODE

1984-1987 Branch Chief, Surgical and Diagnostic Devices Branch
Division of Ophthalmic Devices, ODE

1981-1984 Interdisciplinary Scientist, Division of Ophthalmic Devices, ODE

1979-1981 Research Biologist
Enviro Control, Inc.
Rockville, MD 20852

1976-1979 Clinical Microbiologist
Prince George's General Hospital and Medical Center
Cheverly, MD 20745

Committee Participation

Louis J. Fox Center for Vision Restoration Regulatory Advisor 2015-2016
AdvaMed MTLI Advisory Council 2015-2017
Xavier University MedCon Planning Committee 2013-2017
FDLI Medical Device Committee Chair 2006-2010
FDLI Medical Device Committee 2000-2010
Radiofrequency Identification (RFID) Working Group 2004-2005
Tobacco Legislation Working Group 2004
Project BioShield Implementation Team 2003-2005
Industry Least Burdensome Task Force 2000-2001
CDRH Management Council 1996-2005
FDA Good Guidance Practices Working Group 1996-1997
Management Action Plan Development Team 1993
Human Tissue Products Working Group 1987-1988
Postmarket Product Management Steering Committee 1987

Ophthalmic PMS Committee (Chairperson) 1986-1988
Ophthalmic Program Management System (PMS) Committee 1983-1985

Representative examples of the scope of experience

- As Executive Vice President and Director, Medical Device Practice at Becker & Associates Consulting, Inc., developed and implemented innovative regulatory strategies for new and complex medical technologies from across all medical device panels, including combination products and *in vitro* diagnostics. Prepared premarket submissions including IDEs, 510(k)s, and PMAs. Provided strategic support for clients at Advisory Committee meetings, including review of premarket submissions, classification actions, and dispute resolution panels. Served as an expert witness in support of numerous civil litigation suits including product liability and patent dispute, many for which required testimony and deposition.

- Streamlined premarket evaluation processes and reduced the time required for safe and effective medical devices to receive Agency marketing authorization. In the premarket approval (PMA) program, introduced "modular review," revived product development protocols (PDPs) and instituted numerous procedures designed to streamline agency review and decision-making. In the premarket notification (510(k)) program, applied a "systems approach" to design and institute the most sweeping changes in the history of the program, relying on voluntary standards, guidance documents and design control requirements in lieu of the submission and in-depth analysis of data. In the investigational device exemptions (IDE) program, instituted procedures that have allowed greater access by the American public to promising new and emerging medical technologies while continuing to provide a high level of protection of the rights, safety and welfare of study participants.

- Ensured that the proper statutory and regulatory requirements were consistently applied across all ODE review divisions in the evaluation of 20,000 premarket submissions each year and that the appropriate testing and evaluation was performed on the devices before they were cleared for marketing or permitted to be used in clinical trials.

- As a nationally and internationally recognized authority on all aspects of medical device regulation, provided expert guidance, interpretation, and recommendations to senior Agency and Departmental officials; scientific, medical, and professional personnel, industry representatives; intra/inter-governmental counterparts and others on medical device policies, regulations, and law. Represented the agency at meetings and conferences with Departmental officials; representatives of the regulated industry, healthcare community, national and international scientific and health-related professional organizations; the United States Congress and representatives from foreign governments and Federal, State and local agencies.

- Over a 24 year career with ODE, solved numerous complex regulatory and scientific problems that affected the organization ability to effectively carry out its mission. Accepted numerous short-term assignments to address problem situations, including accumulation of backlogs in pending premarket submissions.

- In November 2002, developed and presented a regulatory strategy for the FDA review of implantable radiofrequency microchips at the National Academy of Sciences. Implemented the strategy involving the Evaluation of Automatic Class III Designation (de novo classification) program resulting in Implantable Radiofrequency Transponder Systems being classified as class II devices, exempt from 510(k) requirements (21 CFR 880.6300).

- In cooperation with AdvaMed's Least Burdensome Industry Task Force, developed and issued the guidance document entitled *The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles*.

- Developed and implemented a regulatory strategy for the approval of a PMA for an implantable pulse generator for the treatment of pain based on preclinical testing and an evaluation of peer reviewed literature. The Genesis™ Neurostimulation (IPG) System by Advanced Neuromodulation Systems, Inc. was evaluated and approved by FDA in less than 180 days (P010032).

- Classified Acute Upper Airway Obstruction Devices through de novo classification process into class II, exempt from 510(k) requirements (K993284) with the exemption principally based on conformance with design control requirements under the quality system regulation (21 CFR 868.5115).

- Developed and implemented an interagency agreement with the Centers for Medicare & Medicaid Services (formerly the Healthcare Finance Administration) for the categorization of all clinical investigations of medical devices permitting reimbursement for a majority of investigational medical devices for the first time in the history of the Medicare program.

- Signed the approval order for the first Humanitarian Device Exemption authorizing distribution of the Harrison Fetal Bladder Stent (Lowery Modification) by Cook OB/GYN® on September 14, 1997 (H960001).

- In cooperation with the medical device industry, developed and issued the guidance document entitled *Deciding When to Submit a 510(k) for a Change to an Existing Device* that addresses which changes or modifications to devices are subject to 510(k) requirements (Blue Book Memorandum K97-1).

- Provided intermittent training for all advisory panel members on the Federal Food, Drug, and Cosmetic Act and medical device regulation.

- Functioned as an expert witness for the government in numerous court cases relating to medical device regulation.

- Provided expert advice to CDRH's Office of Compliance, FDA's Office of General Counsel and the Department of Justice regarding enforcement activities relating to medical devices.

- Functioned as ODE's principal arbiter of scientific and regulatory disputes with the regulated industry regarding decisions affecting individual premarket submissions, including, data requirements, appeals of not filing decisions for PMAs and not substantially equivalent determinations for 510(k)s.

- Developed and implemented the concept of special controls guidance documents for class II devices as a means of promoting abbreviated 510(k) submissions and least burdensome premarket requirements.

- Developed a streamlined guidance document development program, integrating national and international consensus standards, in support of the Commissioner of Food and Drug's Critical Path Initiative to reduce regulatory burden for industry and facilitate the agency's premarket review of medical devices.

- As the Director of Program Operations, provided overall direction, coordination, and advice to the Director, Office of Device Evaluation, the Center Director, and the agency for the establishment, development, and operation of the Office's IDE, PMA, 510(k), and reclassification efforts. Specific responsibilities included the review and evaluation of decisions and recommendations rendered by the ODE review divisions concerning IDEs, PMAs, 510(k)s and reclassification petitions; the development and administration of regulations and guidance documents regarding the Office's program areas; the development, implementation and evaluation of the Office's document tracking system, including data collection and analysis of the Office's overall performance; and being a spokesperson for the Agency on all matters of policy, procedures and requirements pertaining to the premarket evaluation of medical devices.

- As the Interim Director of the Division of General and Restorative Devices, lead and directed the planning, organization and execution of the responsibilities of ODE's largest review division. Responsibilities included; all scientific and regulatory recommendations and decisions made by the division regarding dental, infection control, general hospital, plastic and reconstructive, restorative and orthopedic devices; all recommendations to the Office Director concerning original PMAs and IDEs, as well as petitions for reclassification; and all decisions regarding supplemental IDE and PMA applications and 510(k)s, as well as the activities of the Division's advisory panels.

- As the Acting Deputy Director of the Division of Ophthalmic, lead and managed the Division's investigational device exemption program for all significant risk

ophthalmic device clinical investigations, including investigations involving contact lenses and related products, intraocular lenses and surgical/diagnostic devices. Streamlined the processes by which the Division evaluated all regulatory submissions involving ophthalmic devices.

- As the Chief of the Surgical and Diagnostic Devices Branch within the Division of Ophthalmic Devices, planned and organized the activities of the individual branch members in the review and evaluation of PMAs, IDEs, and 510(k)s involving surgical and diagnostic ophthalmic devices. Developed a broad understanding of the diverse scientific disciplines that are necessary for the responsible regulation of the ophthalmic medical device industry.

- As a team leader in the Division of Ophthalmic Devices, managed review teams responsible for the evaluation of PMAs, IDEs, and 510(k)s. Coordinated the complete scientific and regulatory evaluation of the submissions and made recommendations regarding their approvability to senior Division management.

- As an interdisciplinary scientist, evaluated scientific information and data regarding the safety and effectiveness of ophthalmic medical devices. Functioned principally as a microbiologist, but relied on knowledge in other scientific disciplines to evaluate virtually all aspects of device performance.

- As a board certified Clinical Microbiologist with the American Society of Clinical Pathology (M., A.S.C.P.), performed diagnostic procedures involving the differentiation, isolation and identification of microorganisms from body fluids and sites, insured that quality control criteria were met before computerized patient diagnostic reports were prepared and forwarded to attending physicians, and evaluated new or modified diagnostic techniques and methods.

PROFESSIONAL AFFILIATIONS

Food and Drug Law Institute (FDLI)
Regulatory Affairs Professional Society (RAPS)
American Society of Clinical Pathologists (ASCP)
Food and Drug Administration Alumni Association (FDAAA)

PUBLICATIONS

Phillips PJ. 2015. Sufficiency of Information in 510(k) Summaries. Letter to the Editor. JAMA Intern Med. 175(5):863-864.doi:10.1001/jamainternmed.2015.80

Phillips PJ. 2013. Forward. *Medical Devices Law and Regulation Answer Book 2013*. New York City, NY. Practicing Law Institute. xxix-xxx

Kessler L, Phillips PJ. 2010. Premarket Notification: A Key Element of US Medical Device Regulation. *Public Health Effectiveness of the FDA 510(k) Clearance Process:*

Balancing Patient Safety and Innovation. Workshop Report. Washington, D.C. Institute of Medicine of the National Academies. 75-112

Phillips PJ, Zielinski KM. 2008. Claims and 510(k) requirements: An area of uncertainty for medical devices. *Update* May/June 2008:14-17.

McTyre RB, Suh R, Phillips PJ, Levy B. 2007. On the utility of non-epidemiology data in assisting with interpretation of case-control study results: The Bausch & Lomb case. Submitted for publication, *Annals of Epidemiology*. Atlanta, GA: American College of Epidemiology.

Phillips, PJ and Lynne, JC. 2005. Unnecessary 510(k) Filings: A Waste of FDA and Industry Resources. *Regulatory Affairs Journal (Devices)* 13:341-345.

Brown, RP, Stratmeyer, ME, Alonge, LA, Phillips, PJ. 2003. Use of Safety Assessment to Support Regulatory Decision Making and Risk Communication Efforts in CDRH; DEHP in PVC Medical Devices (W-01). *9th Annual Science Forum-FDA Science: Protecting America's Health- Abstracts,* 189.

Phillips, PJ, Less, JR. 1999. The Development of a New 510(k) Program. *Medical Device & Diagnostic Industry,* 21(6), 151-159.

Marlowe, DE, Phillips, PJ. 1998. FDA Recognition of Consensus Standards in the Premarket Notification Program. *Biomedical Instrumentation & Technology,* 32(3), 301-304.

Phillips, PJ. 1996. EMC Information for Premarket Approval of Medical Devices. *Electromagnetic Compatibility for Medical Devices: Issues and Solutions.* Arlington, VA: Association for the Advancement of Medical Instrumentation.

Phillips, PJ. 1994. Medical Lasers; FDA Review and Regulatory Status. *Medical Laser Marketplace '94.* Nashua, NH: PennWell Publishing Company.

INVITED PRESENTATIONS *(selected)*

18th Annual Meeting of the National Electrical Manufacturer's Association's (NEMA's) Diagnostic Imaging and Therapy Systems Division
San Diego, CA September 1993

Medical Laser Marketplace '94
Los Angeles, CA January 1994

HIMA Meeting on Product Approval Initiatives
Washington, D.C. May 1994

HIMA Board of Directors Meeting
Washington, D.C. June 1994

FDLI Device Update Conference
Washington, D.C. June 1994

Division of Small Manufacturer's Assistance (DSMA) Device Submissions Workshop
Boston, MA July 1994

4th Annual HIMA Device Submissions Workshop
Crystal City, VA July 1994

19th Annual Meeting of NEMA's Diagnostic
Imaging and Therapy Systems Division
Martha's Vineyard, MA September 1994

International Conference on Medical Devices
Minneapolis, MN September 1994

CAL BIO Summit '94
LaJolla, CA October 1994

Biomedical Engineering Society (BMES) Annual Meeting
"Frontiers in Biomedical Engineering"
Tempe, AZ October 1994

HIMA Annual Meeting
Washington, D.C. October 1994

American Society for Cataract and Refractive Surgery
"Congress on Ophthalmic Management"
San Diego, CA April 1995

BIOEAST '95
Washington, D.C. January 1995

American Society for Laser Medicine and Surgery (ASLMS) Annual Meeting
San Diego, CA April 1994

Radiology Centennial Commemorative Conference
National Institutes of Health (NIH)
Bethesda, MD May 1995

FDA: Third-Party Review of Premarket Notifications Workshop
Rockville, MD June 1995

Howard A. Paul Memorial Symposium
Washington, D.C. June 1995

American Academy of Ophthalmology Spring Symposium
Seattle, WA June 1995

FDA/American Association for Medical Instrumentation (AAMI) Electromagnetic Compatibility Conference
Anaheim, CA May 1995

FDLI Medical Device Seminar
Washington, D.C. June 1995

FDLI Medical Device Update
Washington, D.C. June 1995

5th Annual HIMA Device Submissions Workshop
Washington, D.C. July 1995

FDA Southwest Region Grassroots Meeting
Denver, CO August 1995

BIO West '95
San Jose, CA October 1995

NIH Biomaterials and Medical Implant Science Workshop
Bethesda, MD October 1995

FDA Science Advisory Board Meeting
Arlington, VA November 1995

FDA/FDLI Video teleconference
Rockville, MD April, 1996

American Society for Artificial Internal Organs (ASAIO) Annual Meeting
Washington, D.C. May 1996

HIMA Meeting on FDA Advisory Committee Meetings
Washington, D.C. June 1996

Association of Food and Drug Officials (AFDO) Medical Device Workshop
San Francisco, CA June 1996

FDLI Medical Device Update
Washington, D.C. June 1996

6th HIMA Annual Device Submissions Workshop
Washington, D.C. July 1996

FDA Field Committee Meeting
Potomac, MD August 1996

RAPS Annual Meeting
Washington, D.C. September 1996

Medical Alley FDA Seminar
Minneapolis, MN December 1996

HIMA 510(k) Task Force Meeting
Washington, D.C. April 1997

7th Annual HIMA Device Submissions Workshop
Washington, D.C. July 1997

Indiana Medical Device Manufacturers Council
Indianapolis, IN August 1997

HIMA Board of Directors Meeting
Washington, D.C. September 1997

FDA/FDLI Video Teleconference
Rockville, MD October 1997

FDLI Medical Device Update '97
Washington, D.C. December 1997

FDA/FDLI Video Teleconference
Rockville, MD February 1998

Hearing Industry Association Annual Meeting
Sarasota, FL February 1998

ASLMS Annual Meeting
San Diego, CA April 1998

FDA Intended Use Workshop
Rockville, MD June 1998

FDA/FDLI Video teleconference
Rockville, MD July 1998

8th Annual HIMA Device Submissions Workshop
Washington, D.C. July, 1998

FDLI 42nd Annual Educational Conference
Washington, D.C. December 1998

FDLI Medical Device Update 1999
Washington, D.C. March 1999

ASLMS Annual Meeting
Orlando, FL April 1999

9th Annual HIMA Device Submissions Workshop
Washington, D.C. July 1999

RAPS Annual Meeting
Washington D.C. October 1999

Medical Technology Leadership Forum
United States Capitol, Washington, D.C. October 1999

HIMA Workshop "Getting to Market Sooner"
Washington, D.C. December 1999

BEMA Roundtable
Washington, D.C. February 2000

10th Annual AdvaMed Device Submissions Workshop
Washington, D.C. July 2000

Medical Alley Device Workshop
Minneapolis, MN December 2000

AAMI/FDA/AdvaMed Conference on Standards
Rockville, MD January 2001

FDLI/FDA Educational Conference
Washington, D.C. April 2001

11th Annual AdvaMed Device Submissions Workshop
Washington, D.C. June 2001

American College of Cardiology (ACC)/FDA Workshop
Bethesda, MD June 2001

Medical Device Manufacturers Association (MDMA) 2001 Annual Meeting
Washington, D.C. July 2001

RAPS Annual Meeting
Baltimore, MD October 2001

FDLI Annual Conference
Washington, D.C. April 2002

12th Annual AdvaMed Device Submissions Workshop
Rockville, MD June 2002

Human Microchip Symposium
National Academy of Sciences
Washington, D.C. November 2002

FDLI Annual Conference
Washington, D.C. April 2003

13th Annual AdvaMed Device Submissions Workshop
Washington, D.C. June 2003

FDLI Annual Conference
Washington, D.C. April 2004

14th Annual AdvaMed Device Submissions Workshop
Washington, D.C. June 2004

AAMI/FDA/AdvaMed Conference on Standards
Arlington, VA February 2005

CDRH Staff College – Instructor
Rockville, MD 1995-2005

Fiftieth Annual FDLI & FDA Educational Conference: Cutting Edge Innovations: Balancing Safety and Rewards for Healthier Lives
Bethesda, MD April 2007

Second Annual Medical Device Regulatory, Reimbursement and Compliance Congress,
Cambridge, MA March 2007

ILSI Biomed Israel - FDA Today: An Expert Symposium for Scientists, Venture Investors, and Corporate Executives
Tel Aviv, Israel June 2007

AdvaMed conference on The Use of Standards in Submissions
Bethesda, MD November 2007

Regulatory Affairs Professionals Society – Horizons Conference & Exhibit
San Francisco, CA March 2007

Food and Drug Law 101 and Introduction to Medical Device Law and Regulation
Workshop: Understanding How FDA Regulates the Medical Device Industry
Rockville, MD May 2007, 2008

FDLI Annual Meeting
Washington, D.C. May 2008

Regulatory Affairs Professionals Society – Advertising, Promotion and Labeling Conference
Baltimore, MD May 2008

Medical Device Congress
Boston, MA March 2008

Johnson & Johnson Regulatory Affairs Summit
New Brunswick, NJ October 2008

Medical Device Manufacturers Association
San Francisco, CA October 2008

Medical Device Manufacturers Association
Boston, MA March 2009

FDLI Annual Meeting
Washington, D.C. May 2009

House Energy and Commerce Committee
Subcommittee of Health
Washington, D.C. June 2009

Phoenix CEO Conference
Las Vegas, NV October 2009

Morgenthaler Ventures 4th Annual CEO Summit
San Francisco, CA November 2009

Georgetown University
Washington, D.C. February 2010

FDLI Introduction to Food and Drug Law Workshop
Washington, D.C. March 2010

MDMA Premarket Approval and Premarket Notification Seminar
Palo Alto, CA March 2010

FDLI 2010 Annual Meeting
Washington, D.C. April 2010

Institute of Medicine (IOM)
Public Health Effectiveness of the FDA 510(k) Clearance Process: Workshop 1
Washington, D.C. June 2010

AdvaMed 2010: The MedTech Conference
Washington, D.C. October 2010

Medical Technology Learning Institute
National Harbor, MD November 2010

Medtech 10: North Carolina Device Forum
Durham, NC November 2010

AdvaMed Combination Products Workshop
Washington, D.C. March 2011

MDMA Premarket Approval Application (PMA)
and Premarket Notification Submission (510(k)) Seminar
Waltham, MA March 2011

Medcon 2011: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2011

Institute for Health Technology Studies Press Conference Re: Northwestern University Survey, National Press Club
Washington, D.C. May 2011

Medical Device Quality Conference
Rockville, MD June 2011

MD&M East
New York City, NY June 2011

Cleveland FES Center, Metro Health Medical Center
Cleveland, OH September 2011

DiabetesMine Innovation Summit at Stanford University
Palo Alto, CA September 2011

AdvaMed 2011: The MedTech Conference
Washington, D.C. September 2011

AdvaMed 510(k) Submissions Workshop
Washington, D.C. October 2011

U.S. Senate HELP Committee Staff Briefing
Washington, D.C. November 2011

Annual Meeting of the Food, Drug and Cosmetic Section
New York State Bar Association
New York City, NY January 2012

AdvaMed 510(k) Submissions Workshop
Las Vegas, NV February 2012

MDMA's FDA Forum – PMA/510(k) Workshop & FDA Reform: 2012 and Beyond
Cupertino, CA March 2012

Medcon 2012: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2012

Medical Device Quality Conference
Rockville, MD May 2012

FDLI Medical Device Regulation and Litigation Conference
Washington, D.C. June 2012

AdvaMed 2012: The MedTech Conference
Boston, MA October 2012

AdvaMed 510(k) Submissions Workshop
Arlington, VA October 2012

AdvaMed 510(k) Submissions Workshop
Arlington, VA February 2013

FDLI Medical Device Regulation and Litigation Conference
Washington, D.C. March 2013

MDMA's FDA Forum – PMA/510(k) Workshop
Palo Alto, CA March 2013

FDLI 2013 Annual Conference
Washington, D.C. April 2013

Medcon 2013: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2013

Medical Device Quality Conference
Rockville, MD June 2013

MD&M East
Philadelphia, PA June 2013

Cook Medical 50th Anniversary Meeting
Las Vegas, NV July 2013

AdvaMed 510(k) Submissions Workshop
Crystal City, VA October 2013

AdvaMed 510(k) Submissions Workshop
Arlington, VA February 2014

MDMA FDA Forum
Palo Alto, CA March 2014

Medcon 2014: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2014

U.S. House of Representatives Medical Technology Caucus Briefing
Washington, D.C. July 2014

AdvaMed 510(k) Submissions Workshops
Washington, D.C. October 2014

UGA-FDA Conference/ University of Georgia Center for Continuing Education
Athens, GA November 2014

MD&M West
Anaheim, CA February 2015

2015 AAAS Annual Meeting.
San Jose, CA February 2015

AdvaMed 510(k) Submissions Workshops
Washington, D.C. February 2014

Medcon 2015: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2015

FDLI/ABA/MDMA: Medical Device Law: Compliance Issues, Best Practices, and Future Trends
Washington, D.C. October 2015

AdvaMed 510(k) Submissions Strategy Workshop
Washington, D.C. October 2015

RAPS' Regulatory Convergence
Baltimore, MD October 2015

MDMA FDA Forum
Palo Alto, CA March 2016

Medcon 2016: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2016

MDMA FDA Forum
Palo Alto, CA March 2017

Medcon 2017: FDA/Xavier University Medical Center Conference
Cincinnati, OH May 2017

George Washington University
GW School of Medicine and Health Sciences, the GW Law School, and
the European Center of Pharmaceutical Medicine (ECPM)
Washington, D.C. May 2017

AWARDS

FDA Commissioner's Leveraging/Collaboration Award (June 2005) "For participation in Counterterrorism and Emergency Preparedness activities at FDA."

FDA Commendation (September 2004) "For extraordinary effort in assuring the enactment of the Project Bioshield legislation."

FDA Group Recognition Award (April 2004) "For outstanding initiative and teamwork to expedite the many actions needed to successfully implement the Medical Device User Fee and Modernization Act."

FDA Group Recognition Award (April 2004) "For outstanding teamwork in the successful development and implementation of the CDRH Emergency Preparedness Plans."

FDA Commendation (November 2002) "For extraordinary efforts in developing the Medical Device User Fee and Modernization Act of 2002."

DHHS Secretary's Award for Distinguished Service (June 2001) "For outstanding dedication, diplomacy, and diligence in developing the QuIC Errors Report: Doing What Counts for Patient Safety."

FDA Award of Merit (May 1999) "For dramatically increasing efficiency, bringing safe and effective devices to market in an expedient manner, and maximizing the contribution of Agency resources to public health and safety."

National Partnership for Reinventing Government “Hammer Award” (January 1999) “For contribution to building a government that works better and costs less.”

FDA Award of Merit (May 1998) "For significant impact on the programs and personal contributions to the quality of work performed by the Office of Device Evaluation."

FDA Group Recognition Award (May 1998) "For leading the Organizational Transformation efforts within the Center for Devices and Radiological Health."

FDA Group Recognition Award (May 1998) "For exceptional commitment to the public health while concluding a Mutual Recognition Agreement with the European Union."

CDRH Staff College Faculty of the Year Award (March 1998)

FDA Deputy Commissioner's Special Recognition Award (June 1997) "For outstanding contribution to the development of FDA's Good Guidance Practices, which set forth the Agency's procedures for developing, issuing, and using guidance documents."

CDRH Special Recognition Award (May 1997) "For outstanding team work and exceptional performance in developing a process to recognize third-party reviewers in an effort to improve the Agency's review of premarket applications."

U.S. Department of Health and Human Services Secretary's Award for Distinguished Service (June 1996) "For extraordinary accomplishments and outstanding teamwork in developing and implementing a policy for the expanded development and availability of new generation medical devices."

CDRH Reengineering Special Service Award (August and October 1997) "For extraordinary effort and coordination and planning for the development of an improved process as part of the Center for Devices and Radiological Health's Organizational Transformation efforts."

CDRH Special Recognition Award (October 1996) "In appreciation of the efforts leading to the Center's commemoration of the Twentieth Anniversary of the enactment of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act."

FDA Award of Merit (May 1995) "For sustained outstanding performance in providing significant contributions to the regulation of medical devices as a supervisor and spokesperson."

FDA Group Recognition Award (May 1993) "For outstanding performance in gathering and analyzing data used in the development of CDRH's Management Action Plan."

FDA Commendable Service Award (January 1990) "For evaluating and processing a backlog in intraocular lens premarket approval applications.”

FDA Administration's Commendable Service Award (June 1986) "For outstanding resourcefulness in the development and implementation of an effective system to process and review IDE, PMA, and 510(k) submissions for ophthalmic laser devices."

FDA Commendable Service Award (June 1984) "For outstanding performance in evaluating the safety and effectiveness of intraocular lenses."

CONTINUING EDUCATION

Executive Level

Contemporary Executive Development
The George Washington University
Washington, DC 1989

Executive Leadership Development
U. S. Food and Drug Administration
Rockville, MD 1992-93

Issues in Science and Technology
The Brookings Institute
Charlottesville, VA 1994

Others

Equal Employment Opportunity (EEO)
McClure-Lundberg Associates
Rockville, MD 1982

Experimental Statistics
University of the District of Columbia
Silver Spring, MD 1982

Clinical Lasers
Washington, DC 1984

Lasers in Surgery
Laser Institute of America
Cincinnati, OH 1985

The Basic Food and Drug Law Course
Rockville, MD 1985

FDLI 31st Annual Educational Congress
Washington, DC 1987

Regulation of Human Tissue and Organs
Washington, DC 1990

The Safe Medical Device Act of 1990
The Food and Drug Law Institute (FDLI)
Washington, DC 1990

34th Annual FDLI Training Conference
Washington, DC 1990

Ethics Training
Rockville, MD 1992-2002

Health Industry Manufacturers Association (HIMA)
Seminar on the GMP Regulation
Washington, DC 1994

EEO for Supervisors
College Park, MD 1994